### MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: February 8, 2024

ATTENTION: Members, Medical Board of California (Board)

SUBJECT: Physician and Surgeon Health and Wellness Program -

Discussion and Possible Action on Proposed Rulemaking and Proposed Responses to Public Comments Received During the 45-day Public Comment Period on the Originally Noticed Regulatory Text 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, 1357.14, 1357.15, and 1357.16 of, Division 13, of Title 16 of the California

Code of Regulations

FROM: Kerrie Webb, Attorney III

### REQUESTED ACTION:

After review and consideration of the public comments, the proposed responses thereto, and the proposed text for the rulemaking on the Physician and Surgeon Health and Wellness Program (PHWP), determine whether the Board should proceed with the rulemaking to establish the PHWP at this time, or table this item for discussion and possible action at a future meeting.

If the Board decides to proceed with establishing the PHWP through this rulemaking, staff requests that the Board make a motion to:

- 1) Direct staff to proceed as recommended to reject the comments as specified and provide the responses to the comments as indicated in the meeting materials; and
- 2) Direct staff to take all steps necessary to complete the rulemaking process including the filing of the final rulemaking package with the Office of Administrative Law, authorize the Executive Director to make any non-substantive changes to the proposed regulations and the rulemaking documents, and adopt the proposed regulations as noticed 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, 1357.14, 1357.15, and 1357.16 of, Division 13, of Title 16 of the California Code of Regulations to establish the PHWP.

If the Board decides not to proceed with the rulemaking at this time, then the Board may make a motion to table this item for discussion and possible action at a future meeting.

### **BACKGROUND**

Senate Bill (SB) 1177 (Galgiani, Chapter 591, Statutes of 2016), under Business and Professions Code (BPC) section 2340, authorized the Medical Board of California (Board) to establish the PHWP with the goal of providing early identification of and appropriate

interventions to support physicians' rehabilitation from substance abuse. The purpose of the PHWP is to ensure licensees 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 sections 2340.2, 2340.4, and 2340.6 generally set forth the PHWP program requirements. BPC section 2340.2(e) 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 2340.8 establishes the PHWP Account within the Contingent Fund of the Board and requires the Board to adopt regulations to determine the appropriate fee a participant in the PHWP shall pay to the Board. Additionally, this section provides that the Board may use money from its Contingent Fund, subject to appropriation by the Legislature, 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 that the rulemaking to set the fees will be initiated once a vendor for the PHWP is selected.

At the August 25, 2022 Board meeting, the Board reviewed and approved proposed language 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, 1357.14, 1357.15, and 1357.16 of, Division 13, of Title 16 of the California Code of Regulations to establish the PHWP (see Attachment 1), and authorized staff to proceed with the rulemaking process.

Pursuant to the Administrative Procedure Act, the proposed text was noticed for the 45-day comment period on September 29, 2023, and ended on November 14, 2023. On October 27, 2023, Marcus Friedman, Administrative Director with the Consumer Protection Policy Center, made a timely request for a public hearing pursuant to Government Code section 11346.8(a). The hearing was held on November 14, 2023. The Board received numerous public comments in writing, as well as through oral testimony at the hearing. A summary of the written comments and oral testimony, along with the proposed responses, are provided for your review and consideration as Attachment 2. Further, please see Attachment 3 for the actual written comments and Attachment 4 for a transcript of the November 14, 2023 rulemaking hearing.

### STAFF RECOMMENDATION:

Make and approve a motion to take one of the actions suggested on page 1 of this memo.

- **Attachment 1:** PHWP Noticed text approved by the Board on August 25, 2023
- **Attachment 2:** Summary of written comments and oral testimony and proposed responses regarding the PHWP proposed text
- **Attachment 3:** Copies of the written comments received regarding the PHWP proposed text
- **Attachment 4:** Transcript of the November 14 rulemaking hearing regarding the PHWP proposed text

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

### MEDICAL BOARD OF CALIFORNIA

# PROPOSED REGULATORY LANGUAGE Physician and Surgeon Health and Wellness Program

Legend: Added text is indicated with an <u>underline</u>.

Deleted text is indicated by strikeout.

Omitted text is indicated by ...

Amend Sections 1357, 1357.1, and 1357.9; Repeal Sections 1357.2, 1357.3, 1357.4, 1357.5, 1357.6, and 1357.8, Adopt Sections 1357.10, 1357.11, 1357.12, 1357.13, and 1357.14 of Article 2 and Amend section 1361.5(c)(3) of Article 4 of Chapter 2 of Division 13, of Title 16 of the California Code of Regulations to read as follows:

### Article 2. Impaired Physician Program Physician and Surgeon Health and Wellness Program

### § 1357. Definitions.

As used in this article:

- (a) "Program" means the impaired physician diversion program authorized pursuant to Article 14 (commencing with Section 2340) of the Medical Practice Act.
- (b) "Committee" means a diversion evaluation committee.
- (a) "Board" means the Medical Board of California or its designee unless otherwise specified.
- (b) "Clinical Diagnostic Evaluation" includes any exam performed by a licensed physician and surgeon, and used to determine:
  - (1) whether the participant has a substance abuse problem;
  - (2) whether the participant is a threat to themselves or others; and
  - (3) recommendations relating to the participant's treatment, rehabilitation, and/or the participant's ability to practice medicine safely.
- (c) "Conflict of Interest" means having a financial, personal, or familial relationship with the participant, or other relationship that could reasonably be expected to compromise the ability of the other to render impartial and unbiased reports.

- (d) "Contractor" includes a contractor or a subcontractor who contracts to perform services for the vendor, including medical, mental health, laboratory, or other service providers.
- (e) "Employer" includes the participant's employer, supervisor, chief of staff, the health or wellbeing committee chair, or equivalent, as applicable to the participant's practice setting, if any.
- (f) "Full-time practice" means the licensee is not subject to any practice restriction imposed by the program or Board.
- (g) <u>"Licensee" means a California licensed physician and surgeon or a holder of a California physician and surgeon postgraduate training license.</u>
- (h) "Participant" means a licensee enrolled in the program pursuant to a signed agreement with the program, regardless of whether the licensee enrolled pursuant to a condition of probation imposed by the Board, or as a self-referral.
- (i) <u>"Practice restriction" means a restriction from practicing medicine for any period of time or a limitation on any of the following:</u>
  - (1) Number of hours the participant is authorized to practice medicine;
  - (2) Locations where a participant is authorized to practice medicine;
  - (3) The types of services or procedures the participant may perform.
- (j) "Program" means the Physician and Surgeon Health and Wellness Program authorized pursuant to Article 14 commencing with Section 2340 of the code.
- (k) "Vendor" means the entity contracted with the Board to perform services required to administer the program or its designee.

Note: Authority cited: Sections 2018, Business and Professions Code. <u>Reference: Sections 315, 2064.5, 2340, 2340.2, 2340.4, 2340.6, and 2340.8, Business and Professions Code.</u>

### § 1357.1. Criteria for Admission.

An applicant The participant shall meet the following criteria for admission to the program:

- (a) The applicant participant shall be a <u>California</u> licensed physician <u>and surgeon</u> or <u>hold</u> a physician and surgeon postgraduate training license be otherwise legally authorized to practice medicine in this state.
- (b) The applicant participant is found to abuse dangerous drugs substances or alcoholic beverages, or suffer from mental or physical disability in a manner which may affect the

physician's participant's ability to practice medicine safetysafely or competently.

- (c) The applicant participant shall have voluntarily requested admission to the program or have been referred by the Board pursuant to a disciplinary order.
- (d) The applicant participant agrees in writing to undertake any medical or psychiatric examinations ordered to evaluate the application for participation in the program.
- (e) The applicant participant cooperates with the program by providing medical information, disclosure authorizations and releases of liability as may be necessary for participation in the program.
- (f) The participant agrees in writing to abstain from the use of alcohol and prohibited substances as defined in section 1361.51(e).
- (g) The participant agrees in writing to comply with all practice restrictions as defined in section 1357(i) imposed by the program.
- (f)(h) The applicant participant agrees in writing to cooperate with all elements of the diversion agreement for admission into the program, including all sections of this article, and to pay all costs required for participation in the program.

Note: Authority cited: Section 2018, Business and Professions Code. Reference: Sections 315, 2064.5, 2340, 2340.2, 2340.4, 2340.6, and 2340.8 Business and Professions Code.

### § 1357.2. Procedure for Review of Applicants.

- (a) Program staff and a committee, shall act as consultants to the program manager for the purpose of interviewing each applicant who requests admission to the program.
- (b) The committee shall recommend such medical and psychiatric examinations as may be necessary to determine the applicant's eligibility for the program and request such other information, authorizations, and releases necessary for the program.
- (c) The committee shall make a recommendation to the program manager whether the applicant should be admitted to the program.
- (d) The program manager's decision on admission of an applicant to the program shall be final.

Note: Authority cited: Section 2018, Business and Professions Code. Reference: Section 2350. Business and Professions Code.

### § 1357.3. Evaluating Physicians.

A physician selected by the program manager or his/her designee to conduct medical and psychiatric evaluations of an applicant shall be a licensed physician who is competent in his/her field of specialty.

Note: Authority cited: Section 2018, Business and Professions Code. Reference: Section 2350, Business and Professions Code.

### § 1357.4. Causes for Denial of Admission.

The program manager may deny an applicant admission to the program for any of the following reasons:

- (a) The applicant does not meet the requirements set forth in Section 1357.1.
- (b) The applicant has been disciplined by another state medical licensing authority.
- (c) Complaints or information have been received by the division which indicate that the applicant may have violated a provision of the Medical Practice Act or committed any other act that would be grounds for discipline, excluding Sections 822 and 2239 of the code.
- (d) The committee recommends that the applicant will not substantially benefit from participation in the program or that the applicant's participation in the program creates too great a risk to the public health, safety or welfare.

Note: Authority cited: Section 2018, Business and Professions Code. Reference: Sections 2350 and 2354, Business and Professions Code.

### § 1357.5. Causes for Termination from the Program.

The program manager may terminate a physician's participation in the program for any of the following reasons:

- (a) The physician has failed to comply with the diversion agreement, including but not limited to, failure to comply with the prescribed monitoring or treatment regimen, use of alcohol or other unauthorized drug; or refusal to stop practice when directed to do so by the committee.
- (b) Any cause for denial of an applicant in Section 1357.4.
- (c) The physician has failed to comply with any of the requirements set forth in Section 1357.1.
- (d) The committee recommends that the physician will not benefit from further participation in or has not substantially benefited from participation in the program or that the physician's continued participation in the program creates too great a risk to the public health, safety or welfare.

Note: Authority cited: Sections 2018 and 2355, Business and Professions Code. Reference: Sections 2350, 2351 and 2354, Business and Professions Code.

### § 1357.6. Notification of Termination.

Whenever any physician who is self-referred is terminated from the program and has been determined to present a threat to the public health or safety, the program manager shall report such fact to the division, without the inclusion of any confidential information as defined in Section 1357.8.

Note: Authority cited: Section 2018, Business and Professions Code. Reference: Sections 2350 and 2355, Business and Professions Code.

### § 1357.8. Confidentiality of Records.

(a) All board, division, committee and program records relating to a physician's application to the program or participation in the program shall be kept confidential pursuant to Section 2355 of the code, including all information provided by the applicant, or by an examining physician, to the program manager, a medical consultant, members of the committee, or other employees of the division in connection with the program. Except as otherwise provided in section 1357.9, such records shall be purged when a physician's participation in the program is either completed or terminated. (b) All other information or records received by the board prior to the acceptance of the applicant into the program, or which do not relate to the physician's application to the program, or which do not relate to the physician in the program, shall not be maintained in a confidential manner as required by Section 2355 and may be utilized by the board in any disciplinary or criminal proceedings instituted against the physician. Note: Authority cited: Section 2018, Business and Professions Code. Reference: Sections 2346 and 2355. Business and Professions Code.

### § 1357.9. Retention of Diversion Program and Participant Records.

The diversion program shall retain the following types of records in a paper or electronic format that is usable, readable, and searchable (e.g., Microsoft Word, Excel, or a PDF document) for seven (7) years from the date of creation by the program or receipt by the program-concerning a participant:

- (A)(a) All participant intake reports and case analyses.
- (b) All participant agreements and amendments thereto.
- (e)(c) All participant file notes, laboratory and incident reports.
- (d) All other records related to the participant's performance in the program, including medical records, treatment plans, and documents relating to the participant's compliance or noncompliance with the conditions and procedures for treatment and monitoring by the program.
- (e) All correspondence with the Board.
- (f) All correspondence with contractors.
- (c) All correspondence with the Enforcement Program.
- (d) All committee letters.
- (f) Computerized records derived from any of the foregoing types of documents.

Note: Authority cited: Sections 2018-and 2355, Business and Professions Code. Reference: Sections 315, 2340, 2340.2, 2340.4, 2340.6, and 2340.8 2355, Business and Professions Code.

### § 1357.10. Requirements for the Physician and Surgeon Health and Wellness Program Vendor and Participants

- (a) The vendor shall comply with and is responsible for ensuring that all contractors and subcontractors comply with the Board's requirements contained in Article 14 of the Code and this article.
- (b) Participants shall meet the criteria set forth in section 1357.1.
- (c) Clinical Diagnostic Evaluation: If the vendor or Board requires a participant to undergo a clinical diagnostic evaluation, the participant shall comply with, and the evaluator shall meet, all the requirements set forth in section 1361.5(c)(1)(A)-(D). For purposes of this program, references to the "Board" in section 1361.5(c)(1)(A)-(D) shall mean the Board and the vendor for Board-referred participants, and the vendor for self-referred participants. References to "probationary terms and conditions" and "on probation" in section 1361.5(c) shall mean probationary terms and conditions ordered by the Board for Board-referred participants and the terms of the participant's monitoring agreement with the vendor for self-referred participants.
- (d) Notification of Employer or Supervisor Information: If the participant has an employer or supervisor, the participant shall comply with all the notification and consent requirements set forth in section 1361.5(c)(2). For purposes of this program, references to the "Board" in section 1361.5(c)(2) shall mean the Board and the vendor for Board-referred participants, and the vendor for self-referred participants.

### (e) Biological Fluid Testing:

- (1) Participants shall abstain from the use, consumption, ingestion, or administration of prohibited substances, as defined in section 1361.51(e).
- (2) Participants shall comply with and be tested in accordance with all the requirements set forth in section 1361.5(c)(3). For purposes of this program, references to the "Board" in section 1361.5(c)(3) shall mean the Board and the vendor for Board-referred participants, and the vendor for self-referred participants.
  - (A) Notwithstanding section 1361.5(c)(3)(I)(4), tolling shall not be allowed for a self-referred participant, so long as the participant has a license to practice in California. A self-referred participant who is moving their place of residence out of state, however, may transfer monitoring and care to a program in the new location upon the vendor's written approval and in compliance with the requirements of this subsection. The self-referred participant shall have the out-of-state program forward its

reported to the out-of-state program and compliance reports within three
(3) business days of receipt by the out-of-state program to the vendor.

The participant shall take all steps required by the out-of-state program to authorize information sharing with the vendor, including signing any authorization or consent to release test results or compliance reports to the vendor.

Any report to the vendor by the out-of-state program of a major violation as defined in section 1361.52(a) or minor violation as defined in section 1361.52(c) shall be reported in writing to the Board consistent with section 1351.13. Within 10 days prior to returning to California to reside, the self-referred participant shall re-enter into a contract for monitoring and care with the vendor. Upon returning to California, if the self-referred participant has not previously met the full first-year testing frequency requirements, the participant shall be subject to completing a full year at the first-year testing frequency requirements, otherwise the second-year testing frequency requirements shall be in effect.

- (f) Positive Biological Fluid Tests: When a participant tests positive for a prohibited substance, the vendor shall notify the Board of the positive test in writing within one (1) business day of receiving the results.
- (g) Requirements for Testing Locations/Laboratories and Specimen Collectors: The vendor's contractors that provide testing locations, laboratory services, or specimen collection, shall meet all the standards set forth in section 1361.54.

  For purposes of this program, references to the "Board" in section 1361.54 shall mean the Board and the vendor for Board-referred participants, and the vendor for self-referred participants.
- (h) Type of Treatment: In determining whether a participant shall be required to undergo inpatient, outpatient, or other type of treatment, the vendor and its contractors shall consider the following criteria:
  - (1) If the participant is required to undergo a clinical diagnostic evaluation as specified in section 1357.10, the recommendation of the clinical diagnostic evaluation;
  - (2) License type;
  - (3) Participant's history;
  - (4) <u>Documented length of sobriety/time that has elapsed since substance</u> abuse:

- (5) Scope and pattern of substance use;
- (6) Participant's treatment history;
- (7) Participant's medical history and current medical condition;
- (8) Nature, duration, and severity of substance abuse; and
- (9) Whether the participant is a threat to themselves or the public.
- (i) <u>Treatment Providers: A vendor's contractors providing staff and services shall</u> meet all the following requirements:
  - (1) <u>Licensure and/or accreditation by the state agency or other authority</u>
    responsible for the licensure or other regulation of the practice of the
    particular healthcare profession in the state in which the treatment provider
    proposes to practice;
  - (2) A minimum of three (3) years' experience in the treatment and rehabilitation of health professionals with substance abuse problems;
  - (3) Sufficient resources available to adequately evaluate the physical and mental needs of the participant, provide for safe detoxification, and manage any medical emergency;
  - (4) Professional staff who are competent and experienced members of the clinical staff with a minimum of three (3) years' experience in the treatment and rehabilitation of healthcare professionals with substance abuse problems;
  - (5) Treatment planning involving a multidisciplinary approach and specific aftercare plans; and
  - (6) Means to provide treatment and progress documentation to the vendor and Board for Board-referred participants, or to the vendor for self-referred participants consistent with the contract for services. "Means" shall include the staffing, equipment, and procedures in place to meet the requirements of this section.
- (j) Group Support Meeting Facilitators: If the participant is required to participate in support group meetings, the participant shall comply with, and the facilitator shall meet, all the requirements set forth in section 1361.5(c)(4). For purposes of this program, references to the "Board" in section 1361.5(c)(4) shall mean the Board and the vendor for Board-referred participants, and the vendor for self-

### referred participants.

- (k) Worksite Monitors: If the participant is required to have a worksite monitor, the participant shall comply with, and the monitor shall meet, all the requirements set forth in section 1361.5(c)(5). For purposes of this program, references to the "Board" in section 1361.5(c)(5) shall mean the Board and the vendor for Board-referred participants, and the vendor for self-referred participants.
- (I) Return of Participant to Practice: If participant has been restricted from full-time practice, the participant shall meet all the requirements of section 1361.53 prior to a determination being made to return the participant to full-time practice or returning to practice with restrictions. For purposes of this program, references to the "Board" in section 1361.53 shall mean the Board and the vendor for Board-referred participants, and the vendor for self-referred participants; references to "probation" in section 1361.53 shall mean probation ordered by the Board for Board-referred participants, and the terms of the participant's monitoring agreement with the vendor for self-referred participants.

Note: Authority cited: Sections 2018 and 2340, Business and Professions Code. Reference: Sections 315, 315.2, 315.4, 2340, 2340.2, 2340.4, 2340.6 and 2340.8, Business and Professions Code.

### § 1357.11. Report and Public Disclosure of Practice Restrictions for Participants

If a vendor imposes a practice restriction on a participant, the vendor shall report it in writing to the Board within one (1) business day, and the Board shall make the following information public on the participant's profile on the Board's website: 1) the participant's name; 2) whether the participant's license is restricted or in a non-practice status; 3) a detailed description of each restriction imposed. If the participant self-referred, and enrollment in the program was not a condition of probation, then the public disclosure shall not contain information that the restriction or non-practice status is the result of the participant's enrollment in the program. The Board shall remove the practice restriction from the participant's profile within one (1) business day of the Board's receipt of written notice from the vendor that the practice restriction has been lifted.

Note: Authority cited: Sections 2018, Business and Professions Code. Reference: Sections 315, 315.2, 315.4, 2340, 2340.2, 2340.4 and 2340.6, Business and Professions Code.

### § 1357.12. Reports of Participant Violations, Withdrawals, and Terminations to the Board; Inquiries by the Board

(a) The vendor shall report in writing to the Board each major violation by a participant, as defined in section 1361.52(a), within one (1) business day of the vendor's finding that the participant committed a major violation, and shall

- identify the name and license number of the participant, and a detailed description of the violation(s), including the type and date of each occurrence.
- (b) The vendor shall report in writing to the Board each minor violation by a participant, as defined in section 1361.52(c) within five (5) business days of the vendor's finding that the participant committed a minor violation, and shall identify the name and license number of the participant, and a detailed description of the violation(s), including the type and date of each occurrence.
- (c) The vendor shall report in writing to the Board any participant who withdraws or is terminated from the program within one (1) business day of the withdrawal or termination, and shall identify the name and license number of the participant, the date the participant enrolled in the program, the date of the withdrawal or termination from the program, and a description of the circumstances leading up to the withdrawal or termination.
- (d) If the Board inquires as to whether a licensee is a participant in the program after initiating an investigation on the licensee, the vendor shall provide a written response within three (3) business days of the inquiry indicating whether the licensee is a participant in the program.

Note: Authority cited: Sections 2018, Business and Professions Code. Reference: Sections 315, 315.2, 315.4, 2340, 2340.2, 2340.4 and 2340.6, Business and Professions Code.

### § 1357.13. Vendor Communication with the Board; Annual Reports

- (a) Within 30 days of receiving a written request by the Board, the vendor shall provide a written report containing the following de-identified information:
  - (1) The number of participants currently enrolled in the program;
  - (2) The number of participants who self-referred;
  - (3) The number of participants who were referred by the Board as a condition of probation;
  - (4) The number of participants who have successfully completed their agreement period;
  - (5) The number of participants who successfully returned to practice:
  - (6) The number of participants who withdrew from the program, and the reasons therefor:

- (7) The number of participants who were terminated from the program, and the reasons therefor;
- (8) The number of participants who committed a major violation as defined in section 1361.52(a), or minor violation as defined in section 1361.52(c), and the types of violations committed;
- (9) The number of patients harmed by a participant while the participant was enrolled in the program. For purposes of this section, "patient harm" means injury or death to a patient caused by the participant's violation of the Medical Practice Act or Medical Practice Regulations established by admission, or by Board decision or order issued after an action taken pursuant to the procedures set forth in the Administrative Procedure Act (Section 11500 et seq. of the Government Code);
- (10) The number and types of reports filed with the Board pursuant to section 1357.12;
- (11) A list of contractors performing treatment or other services for program participants, a description of the services they are contracted to perform, and the number of participants assigned to each;
- (12) The number of participants whose families received services through the program, including the types of services received (e.g., individual counseling, group therapy, etc.), and how many times services were provided;
- (13) The number and types of educational events provided by the vendor, the dates provided, and the number of licensees and other interested parties in attendance. For purposes of this section, "educational events" includes seminars, webinars, distribution of written materials, and any other activity designed to assist with the recognition and prevention of physical, emotional, and psychological problems of licensees.
- (14) Any other program statistics requested in writing by the Board regarding compliance with this article, including statistics showing a subcontractor's compliance with the Board's requirements contained in Article 14 of the Code and this article.
- (b) With regard to subdivisions (a)(1) through (a)(12) the report for each category shall include the specific types of substance abuse problems for which treatment is or was being sought (e.g., cocaine, alcohol, Demerol, etc.).

(c) On a yearly basis, on or before August 31, the vendor shall provide all of the data identified in subdivisions (a) and (b) to the Board for inclusion in the Board's annual report.

Note: Authority cited: Sections 2018, Business and Professions Code. Reference: Sections 315, 315.2, 315.4, 2340, 2340.2, 2340.4 and 2340.6, Business and Professions Code.

### § 1357.14. External Independent Audits; Responses to Findings; Grounds for Termination; Transfer of Care

- (a) At least once every three (3) years, and at any other time requested by the Board with at least 90 days' notice from the Board, an external, independent audit shall be conducted by a qualified reviewer or review team from outside the Department of Consumer Affairs with no conflict of interest with the vendor (i.e., no reviewer or individual on a review team has a current or prior business, personal, or financial relationship with the vendor or any employee or officer of the vendor) providing the monitoring services. In addition, the reviewer shall not be a part of or under the control of the Board. The independent reviewer or review team must consist of licensed certified public accountant(s) or public accountant(s) who have at least five (5) years' experience in the professional practice of internal auditing and assessment processes and are qualified to perform audits of monitoring programs. The cost of the audits shall be borne by the vendor and factored into each participant's fee.
- (b) The audit must assess the vendor's performance in adhering to the contract requirements applicable to the program. The auditor must provide a written report of their findings to the Board by June 30 of each three (3)-year period referenced in subsection (a) ("triennial report"), or within 60 days of completing an audit requested by the Board. The report shall not identify participants by name, but shall identify any material inadequacies, deficiencies, irregularities, or other non-compliance with the terms of the vendor's contract with the Board or identify any treatment or monitoring services provided by the vendor that would, in the opinion of the auditor, interfere with the Board's mandate of public protection (collectively referred to herein as "deficiencies"). The report shall further recommend a corrective action plan for each identified deficiency, if any.
- (c) The vendor shall respond to the findings in the audit report in writing to the Board no later than September 1 for each triennial report, or within 60 days of receiving an audit report requested by the Board. If deficiencies were identified in the audit report, then within 60 days of receiving the vendor's response, the Board shall indicate whether and when the contract with the vendor will be terminated along with the reasons therefore, or whether the vendor will be given the opportunity to cure the deficiencies. If the vendor will be given the opportunity to cure the deficiencies, the vendor shall provide a written plan

- within 30 days of the Board's request, identifying how each deficiency will be addressed and in what time period. The Board shall determine whether to reject, modify, or approve the plan within 30 days of receipt. The Board may extend the deadlines in this section for purposes of consulting with one or more experts or for other good cause.
- (d) Failure of the vendor to cure all deficiencies within the timeframes set by a plan approved by the Board in subsection (c) shall subject the vendor to termination. Termination of the vendor shall be in the sole discretion of the Board.
- (e) As part of its contract with the Board, the vendor shall have a written plan approved by the Board for transferring care and monitoring of participants if its contract with the Board is terminated, including a plan for transferring participant or other records required by this Article to another vendor designated by the Board.

Note: Authority cited: Sections 2018, Business and Professions Code. Reference: Sections 315, 315.2, 315.4, 2340, 2340.2, 2340.4, 2340.6 and 2340.8, Business and Professions Code.

### § 1361.5. Uniform Standards for Substance-Abusing Licensees.

. . .

### Amendment only to section 1361.5, subdivision (c)(3) as follows:

- (3) Biological Fluid Testing.
  - (A) The Board shall require biological fluid testing of substance-abusing licensees.
  - (B) For the purposes of this section, the terms "biological fluid testing" and "testing" mean the acquisition and chemical analysis of a licensee's urine, blood, breath, or hair.
  - (C) The Board may order a licensee to undergo a biological fluid test on any day, at any time, including weekends and holidays. Additionally, the licensee shall be subject to 52-104 random tests per year within the first year of probation, and 36-104 random tests per year during the second year of probation and for the duration of the probationary term, up to five (5) years. If there has been no positive biological fluid tests in the previous five (5) consecutive years of probation, testing may be reduced to one (1) time per month.
  - (D) Nothing precludes the Board from increasing the number of random tests to the first-year level of frequency for any reason, including, but not limited to, if the Board finds or has suspicion that a licensee has committed a violation of the Board's

testing program or has committed a violation as identified in section 1361.52(a), in addition to ordering any other disciplinary action that may be warranted.

- (E) The scheduling of biological fluid testing shall be done on a random basis, preferably by a computer program, except when testing on a specific date is ordered by the Board or its designee.
- (F) The licensee shall be required to make daily contact with the Board or its designee to determine if biological fluid testing is required. The licensee shall be tested on the date of the notification as directed by the Board or its designee.
- (G) Prior to changing <u>testing frequency or</u> testing locations for any reason, including during vacation or other travel, <u>any</u> alternative testing <u>schedule and testing</u> locations must be approved by the Board and meet the requirements set forth in section 1361.54.
- (H) The cost of biological fluid testing shall be borne by the licensee.
- (I) Exceptions to Testing Frequency Schedule.
  - 1. Previous Testing Orders/Sobriety. In cases where the Board has evidence that a licensee has participated in a treatment or monitoring program requiring random testing prior to being subject to testing by the Board, the Board may give consideration to that testing in altering the Board's own testing schedule so that the combined testing is equivalent to the requirements of this section.
  - 2. Violation(s) Outside of Employment. A licensee whose license is placed on probation for a single conviction or incident or two convictions or incidents spanning greater than seven years from each other, where those violations did not occur at work or while on the licensee's way to work, where alcohol or drugs were a contributing factor, may bypass the first-year testing frequency requirements and participate in the second-year testing frequency requirements.
  - 3. Not Employed in Health Care Field. The Board may reduce the testing frequency to a minimum of 12 times per year for any licensee who is not practicing or working in any health care field. If a reduced testing frequency schedule is established for this reason, and if a licensee wants to return to practice or work in a health care field, the licensee shall notify and secure the approval of the Board. Prior to returning to any health care employment, the licensee shall be required to test at the first-year testing frequency requirement for a period of at least 60 days. At such time the person returns to employment in a health care field, if the licensee has not previously met the first-year testing frequency requirement, the licensee shall be required to test at the first-year testing frequency requirement for a full year before he or she may be reduced to testing frequency of at least 36 tests per year.
  - 4. Tolling. A Board may postpone all testing for any licensee whose probation is placed in a tolling status while the licensee is not residing in California, provided

the overall length of the probationary period is also tolled. A licensee shall notify the Board upon the licensee's return to California and shall be subject to biological fluid testing as provided in this section. If the licensee returns to employment in a health care field and has not previously met the first-year testing frequency requirements, the licensee shall be subject to completing a full year at the first-year testing frequency requirements, otherwise the second-year testing frequency requirements shall be in effect.

- 5. Substance Abuse Disorder Not Diagnosed. In cases where no current substance abuse disorder diagnosis is made, a lesser period of monitoring and biological fluid testing may be adopted by the Board, but shall not be less than 24 times per year.
- 6. Licensed Supervision During Practice. The Board may reduce testing frequency to a minimum of 24 times per year for any person who is a practicing licensee if the licensee receives a minimum of 50% supervision per day by a supervisor licensed by the Board.
- (J) Reinstatement of License or Reduction of Penalty. Nothing herein shall limit the Board's authority to reduce or eliminate the penalties herein pursuant to a petition for reinstatement or reduction of penalty filed pursuant to Government Code section 11522.

. . .

Note: Authority cited: Sections 315, 315.2, 315.4 and 2018, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4, 2227, 2228, 2229, and 2234, and 2340.2, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

From: Abril Dozal

To: Regulations, MBC@MBC
Subject: PSHWP Public Comment

**Date:** Tuesday, November 7, 2023 3:57:33 PM

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#### Hi Alexandria,

SEIU/CIR would like to submit the following comment regarding the proposed regulatory action concerning the Physician and Surgeon Health and Wellness Program being heard on Nov 14th:

Resident and Fellow Physicians represented by the Committee of Interns and Residents (CIR)/SEIU support the creation of the Physician and Surgeon Health and Wellness Program (PHWP) in California. We value the efforts by the state to provide resources to and support rehabilitation of physicians struggling with substance use. However, the proposed fees to be imposed on the physician are impossible for physicians in training to afford. The average salary of a resident/fellow physician and the high cost of living in California means that our trainees live paycheck to paycheck and would go further into debt or experience worsened food/housing insecurity if asked to pay the fees necessary for obtaining treatment in the PHWP. We request that the proposal be amended to provide a significantly reduced fee structure reflective of resident physician pay compared to attending physicians pay.

#### Thanks,

#### Abril Dozal (She/Her) Political Coordinator

Political Coordinato c. 323-485-4513





November 13, 2023

Ms. Alexandria Schembra Associate Program Analyst Medical Board of California 2005 Evergreen Street, Ste. 1200 Sacramento, CA. 95815

Dear Ms. Schembra:

Consumer Watchdog has reviewed the Physician and Surgeon Health and Wellness Program (PHWP) proposed regulatory language with the intention to ensure that the Uniform Standards for Substance Abusing Licensees is fully implemented as SB 1441 (Ridley-Thomas) requires. As SB 1441 (Ridley Thomas) states, each Board shall use the Uniform Standards in dealing with substance abusing licensees whether or not there is a Diversion program meaning that the Uniform Standards must be adhered to by self-referred applicants as well as Board-referred applicants. The Uniform Standards were developed to protect consumers while also providing key protections for doctors to guide their participation in the program ensuring they are able to competently practice medicine safely.

We have found various sections in the proposed regulations that does not explicitly state where the participant, the program, and/or the Board should follow the uniform standards. Although the program overview states that the PHWP shall comply with the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees (Uniform Standards), the regulations must be specific in citing the standards that must be followed in each and every section of the code of regulations. Per CCR Title 16, 1361.5 the Board shall use the Uniform Standards for Substance-Abusing Licensees as provided in section 1361.5 without deviation for each individual determined to be a substance-abusing licensee. To ensure that the PHWP, the participant, and the board follows the laws we are submitting our changes to the proposed PHWP regulatory language. Our changes can be found in bold type as follows:

CCR Title 16, Section 1357.1 – Criteria for Admission: An applicant shall meet the following criteria for admission to the program:

- (b) The <u>participant</u> is found to abuse **dangerous drugs**, <u>substances</u>, or alcoholic beverages in a manner which may affect the participant's ability to practice medicine safely or competently.
- (c) The participant shall have voluntarily requested admission to the program or have been referred by the Board pursuant to a disciplinary order. The criteria need to specify that when a participant enters a program in any manner whether voluntarily, by board disciplinary order, or by a court order that the Uniform Standards are initiated.

EXPOSE, CONFRONT, CHANGE,

- (d) The <u>participant</u> agrees <u>in writing</u> to undertake any medical or psychiatric examinations ordered to evaluate the application for participation in the program. This criteria needs to specify that whenever the Board orders a licensee to undergo a clinical diagnostic evaluation, the Board shall order the licensee to cease practice pending the results of the clinical diagnostic evaluation and review by the Board.
- (f) The participant agrees in writing to abstain from the use of alcohol and prohibited substances as defined in section 1361.51 (e) and that failure to do so will be require the participant to restart biological fluid testing on any day, at any time, including weekends and holidays per the first-year standard of 52-104 random tests per year.
- (g) The participant agrees in writing to comply with all practice restrictions as defined in section 1357(i) imposed by the program. The criteria must include a cease practice order upon entrance into the program.
- (h) The <u>participant</u> agrees in writing to cooperate with all elements of the agreement <u>for</u> admission into the <u>program</u>, including all sections of this article and to pay all costs required for <u>participation in the program</u>. This section must include all elements of the agreement including abiding by the uniform standards for admission into the program.

1357.4 Causes for Denial of Admission.

This section should not be deleted.

The following sections of 1357.4 must be included in the regulations:

- (b) The applicant has been disciplined by another state medical licensing authority specifically that the applicant has surrendered or had had a license revoked by another state medical licensing authority.
- (c) The applicant has violated Sections 822 and 2239 of the business and professions code.
- (d) The committee recommends that the applicant will not substantially benefit from participation in the program or that the applicant's participation in the program creates too great a risk to the public health, safety, or welfare.

1357.5 Causes for Termination from the Program.

The following sections of 1357.5 must be included in the regulations:

The program manager may terminate a physician's participation in the program for any of the following reasons:

- (a) The applicant has failed to comply with the agreement (and the Uniform Standards), including but not limited to, failure to comply with the prescribed monitoring or treatment regimen, use of alcohol or other unauthorized drug; or refusal to stop practice when directed to do so by the committee. This must remain in the regulations.
- (b) Any cause for denial of an applicant in Section 1357.4 which includes:

The program manager may deny an applicant admission to the program for any of the following reasons:

- (a) The applicant does not meet the requirements set forth in Section 1357.1.
- (b) The applicant has been disciplined by another state medical licensing authority.
- (c) Complaints or information have been received by the division which indicate that the applicant may have violated a provision of the Medical Practice Act or committed any other act that would be grounds for discipline, excluding Sections 822 and 2239 of the code.
- (d) The committee recommends that the applicant will not substantially benefit from participation in the program or that the applicant's participation in the program creates too great a risk to the public health, safety or welfare. *Cal. Code Regs. Tit. 16, § 1357.4*
- d. The committee recommends that the applicant will not benefit from further participation in or has not substantially benefitted from participation in the program or that the applicant's continued participation in the program creates too great a risk to the public health, safety, or welfare.

1357.6 Notification of Termination.

The following section of 1357.6 must be included in the regulations:

Whenever any applicant who is self-referred is terminated from the program and has been determined to present a threat to the public health or safety, the program manager shall report such fact to the division and the board, without the inclusion of any confidential information. When reporting a termination to the board, the Uniform Standards are implemented.

1357.9. Retention of Program and Participant Records.

The following must be included in the regulations of program documents that must be retained for 7 years from the date of creation by the program:

- c) All correspondence with the Enforcement Program.
- d). All committee letters.

f) Computerized records derived from any of the foregoing types of documents.

### 1357.10. Requirement for the Physician and Surgeon Health and Wellness Program Vendor and Participants

- (a). The vendor shall comply with and is responsible for ensuring that all contractors and subcontractors comply with the Board's requirements contained in Article 14 of the Code, all sections of the Uniform Standards, and this article.
- (b) Participants shall meet the criteria set forth in section 1357.1 including agreeing to a cease practice order and agrees to cooperate and comply with all of the Uniform Standards.
- (c) Clinical Diagnostic Evaluation: If the vendor or Board requires a participant to undergo a clinical diagnostic evaluation, the participant shall comply with, and the evaluator shall meet all the requirements set forth in section 1361.5 © (1) (A) − (D). For purposes of this program, references to the "Board" in section 1361.5 (c) (1) (A) − (D) shall mean the Board and the vendor for Board-referred participants, and the vendor for self-referred participants. References to "probationary terms and conditions" and "on probation" in section 1361.5 (c) shall mean probationary terms and conditions ordered by the Board for Board-referred participants and the terms of the participant's monitoring agreement with the vendor for self-referred participants. The vendor or Board should require all participants to undergo a clinical diagnostic evaluation as a requirement to participate in the program. Whether the participant is self-referred or board-referred, the vendor or the Board, and the participant must comply with the Uniform Standards.

### (e) Biological Fluid Testing

All of the regulations related to biological testing must require participants to comply with the Uniform Standards whether the participant is a self-referral or referred by the board.

2A). Notwithstanding section 1361.5 (c) (3) (I) (4), tolling shall not be allowed for a self-referred participant, so long as the participant has a license to practice in California. A self-referred participant who is moving their place of residence out of state, however, may transfer monitoring and care to a program in the new location upon the vendor's written approval and in compliance with the requirements of this subsection. The self-referred participant shall have the out-of-state program forward its testing results within (3) business days of the results being reported to the out-if-sate program and compliance reports within three (3) business days of receipt by the out-of-state program to the vendor. The participant shall take all steps required by the out-of-state program to authorize information sharing with the vendor, including signing any authorization or consent to release test results or compliance reports to the vendor.

Any report to the vendor by the out-of-state program of a major violation as defined in section 1361.52 (a) or minor violation as defined in section 1361.52 (c) shall be reported in writing to the Board consistent with section 1351.13. Within 10 days prior to returning to California to reside, the self-referred participant shall re-enter into a contract for monitoring and care with the vendor. Upon returning to California, if the self-referred participant has not previously met the full first-year testing frequency requirements, the participant shall be subject to completing a full year at the first-year testing frequency requirements, otherwise the second-year testing frequency requirements shall be in effect and the participant will adhere to a cease practice order and comply to all elements of the Uniform Standards.

- (f) Positive Biological Fluid Tests: When a participant tests positive for a prohibited substance, the vendor shall notify the Board of the positive test in writing within one (1) business day of receiving the results and the vendor and the participant will adhere to the Uniform Standards.
- (g) Requirements for Testing Locations/Laboratories and Specimen Collectors: The vendor's contractors that provide testing locations, laboratory services, or specimen collection, shall meet all the standards set forth in section 1361.54. For purposes of this program, references to the "Board" in section 1361.54 shall mean the Board and the vendor for Board-referred participants, and the vendor for self-referred participants. Whether the participant is board-referred or a self-referral, the vendor and the participant must comply with the Uniform Standards.
- (h) Type of Treatment: In determining whether a participant shall be required to undergo inpatient, outpatient, or other type of treatment, the vendor and its contractors shall consider the following criteria:
- (i) The <u>participant</u> agrees in writing to cooperate with all elements of the agreement <u>for</u> admission into the program including all sections of this article, and to pay all costs required for participation in the program.
  - (1) If the participant is required to undergo a clinical diagnostic evaluation as specified in section 1357.10, the recommendation of the clinical diagnostic evaluation. All participants whether self-referred or board referred must undergo a clinical diagnostic evaluation and comply with the Uniform Standards:
  - (3). <u>Participant's history</u> (If a participant has lapsed while in the program with a failed biological fluid test, a missed biological fluid test, or a fraudulent biological fluid test, the participant must adhere to the Uniform Standards):
- (4). Documented length of sobriety/time that has elapsed since substance abuse (If a participant's sobriety has lapsed while in the program, the participant must comply with the Uniform Standards and adhere to a cease practice order and start over with the first-year testing schedule):

- (9). Whether the participant is a threat to themselves or the public. If the participant is a threat to themselves or the public, the vendor must report the participant to the board and the board must issue a cease practice order and suspend the license until the participant is fit to practice medicine.
  - (j) <u>Treatment Providers: A vendor's contractors providing staff and services shall meet all the following requirements:</u>
- (5). Treatment planning involving a multidisciplinary approach and specific aftercare plans; and which comply with the Uniform Standards.
- (l) Return of Participant to Practice: If participant has been restricted from full-time practice, the participant shall meet all the requirements of section 1361.53 prior to a determination being made to return the participant to full-time practice or returning to practice with restrictions. For purposes of this program, references to the "Board" in section 1361.53 shall mean the Board and the vendor for Board-referred participants, and the vendor for self-referred participants; references to "probation" in section 1361.53 shall mean probation ordered by the Board for Board-referred participants, and the terms of the participant's monitoring agreement with the vendor for self-referred participants. Whether the participant is self-referred or board referred, the participant must comply with all of the Uniform Standards and that must be taken into consideration when the decision is made on whether the participant should return to practice.

### 1357.11. Report and Disclosure of Practice Restrictions for Participants

If a vendor imposes a practice restriction on a participant, the vendor shall report it in writing to the Board within one (1) business day, and the Board shall make the following information public on the participant's profile on the Board's website: 1). The participant's name 2) whether the participant's license is restricted or in a non-practice status (it must be listed under secondary status on the physician profile) 3) a detailed description of each restriction imposed. If the participant self-referred and the enrollment in the program was not a condition of probation, then the public shall not contain information that the restriction or non-practice status is the result of the participant's enrollment in the program (the cease practice order or practice restriction must still be listed under the secondary status on the physician profile). The Board shall remove the practice restriction from the participant's profile but not from the board enforcement documentation itself because a practice restriction whether the applicant is self-referred or board referred would call for the board to start the enforcement process, investigate the physician.

### 1357.12. <u>Reports of Participant Violations, Withdrawals, and Terminations to the Board;</u> Inquiries by the Board

(a) The vendor shall report in writing to the Board each major violation by a participant, as defined in Section 1361.52 (a), within one (1) business day of the vendor's finding that the participant committed a major violation, and shall identify the name and

- license number of the participant, and a detailed description of the violation(s), including the type and date of each occurrence and the applicant and the board must follow the Uniform Standards meaning the participant will be ordered to cease practice, the applicant must undergo a new clinical diagnostic evaluation, the applicant must test negative for at least a month of continuous drug testing before being allowed to go back to work, or termination of agreement, and referral for discipline.
- The vendor shall report in writing to the Board each minor violation by a participant, as defined in section 1361.52 (c) within five (5) business days of the vendor's finding that the participant committed a minor violation, and shall identify the name and license number of the participant, and a detailed description of the violation(s), including the type and date of each occurrence and the applicant and the board must follow the Uniform Standards meaning the Board can remove the participant from practice, place practice limitations on the participant, require supervision, increase documentation, issue a citation or fine, require reevaluation/testing, or other action determined by the Board.
- (c) The vendor shall report in writing to the Board any participant who withdraws or is terminated from the program within one (1) business day of the withdrawal or termination, and shall identify the name and license number of the participant, the date the participant enrolled in the program, the date of the withdrawal or termination from the program, and a description of the circumstances leading up to the withdrawal or termination. The board shall follow the uniform standards and investigate the reason for the termination, issue a cease practice order, and take potential further action on the participant's license.
- If the Board inquires as to whether a licensee is a participant in the program after initiating an investigation on the licensee, the vendor shall provide a written response within three (3) business days of the inquiry indicating whether the licensee is a participant in the program and the Board shall comply with the Uniform Standards commencing with a cease practice order.

### 1357.13. Vendor Communication with the Board: Annual Reports

- (a) Within 30 days of receiving a written request by the Board, the vendor shall provide a written report containing the following de-identified information:
   (15). The number of times the Uniform Standards were use and which regulations from the Uniform Standards that the vendor utilized. The number of Uniform Standards that the applicants did not comply with, and which Uniform Standards did they not adhere to.
- 1361.5. Uniform Standards for Substance-Abusing Licensees.

### Amendment only to section 1361.5, subdivision © (3) as follows:

- (2) Biological Fluid Testing
- (I) Exceptions to Testing Frequency Schedule. Licensed Supervision During
  Practice. The Board may reduce testing frequency to a minimum of 24 times per
  year for any person who is a practicing licensee if the licensee receives a
  minimum of 50 % supervision per day by a supervisor licensed by the Board.
  This reduction in testing frequency was meant for other health care licensees
  whose salaries were not equivalent to physicians (i.e., Respiratory
  Therapists). Any physician on probation could fall into the minimum of 50%
  supervision per day based on the license violations which placed them on
  probation. The intent of the reduction in testing frequency was not meant
  for physicians. The biological fluid testing schedules for the first year and
  second year should not change for physicians and the Uniform Standards
  must be followed.

As we stated previously, the Uniform Standards were implemented and placed into regulations to protect consumers and physicians in the program that want to curb their addictions for their patients and for their own well-being. In order to make sure that the PHWP is safe for all stakeholders, the vendor, the applicant, and the Board, the regulations must be drafted to explicitly state where the Uniform Standards should be followed, by which party, and any consequences listed in the Uniform Standards if any party fails to comply.

We anticipate that you will accept our changes to the PHWP proposed regulations. As always, we look forward to working with the Board and the Executive Staff on these changes and are available to respond to any questions or concerns. I can be reached at 310-977-6393 or by email at michele@consumerwatchdog.org.

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Michele Monserratt-Ramos Kathy Olsen Patient Safety Advocate Consumer Watchdog



November 13, 2023

Ms. Alexandria Schembra Associate Program Analyst Medical Board of California 2005 Evergreen St., Ste. 1200 Sacramento, CA 95815

Re: Testimony of the Consumer Protection Policy Center – Physician and Surgeon

Health and Wellness Program

Dear Ms. Schembra:

On behalf of the Consumer Protection Policy Center (CPPC) at the University of San Diego School of Law, I am pleased to submit the following testimony to the Medical Board of California regarding proposed regulations creating a Physician and Surgeon Health and Wellness Program (PHWP).

### **CPPC** Expertise Regarding the Medical Board of California

CPPC is a nonprofit, nonpartisan academic and advocacy center based at the University of San Diego School of Law. For 43 years, CPPC has examined and critiqued California's regulatory agencies that regulate business, professions, and trades, including the Medical Board of California (MBC) and other Department of Consumer Affairs (DCA) health care boards. CPPC's expertise has long been relied upon by the Legislature, the executive branch, and the courts where the regulation of licensed professions is concerned. For example, after numerous reports of problems at MBC's enforcement program were published in 2002, the DCA Director appointed CPPC's then-Administrative Director, Julianne D'Angelo Fellmeth, to the position of MBC Enforcement Monitor pursuant to Business and Professions Code section 2220.1 (now repealed). Over a two-year period, she directed an in-depth investigation and review of MBC's enforcement program and its so-called "diversion program" which purported to monitor substance-abusing licensees. In two exhaustive reports, CPPC's Administrative Director made 65 concrete recommendations to strengthen the Board's programs.

<sup>&</sup>lt;sup>1</sup> Julianne D'Angelo Fellmeth and Thomas A. Papageorge, <u>Initial Report of the Medical Board Enforcement Program Monitor</u> (Nov. 1, 2004); Fellmeth and Papageorge, <u>Final Report of the Medical Board Enforcement Program Monitor</u> (Nov. 1, 2005).

With regard to the diversion program, the Enforcement Monitor found that all of the monitoring mechanisms by which it purported to monitor substance-abusing physicians — including required biological fluid testing, required group therapy meeting attendance, worksite monitor requirements and reporting, and treating psychotherapist reporting — were failing; that the program lacked sufficient internal controls to alert program staff to these failures; and that the program had been so under-resourced and understaffed that staff could not have corrected these failures even if they detected them. Of critical importance, the Monitor also found that the program suffered from an absence of enforceable rules or standards to which participants and personnel were consistently held because MBC itself — contrary to applicable provisions in the Business and Professions Code — had failed to exercise any meaningful oversight over the program. These findings echoed the results of three earlier audits of the program by the Auditor General.<sup>2</sup>

Following the publication of the Enforcement Monitor's reports in 2004 and 2005, the Legislature directed the State Auditor to re-audit MBC's diversion program. In June 2007, the Auditor released Report 2006-116R, which concluded that while the program had improved since the 2005 Enforcement Monitor report, many of the problems identified by the Enforcement Monitor had not been corrected. Specifically, the program failed to ensure that all participants were randomly drug tested; failed to adequately monitor and/or require reporting from its various contractors (including urine specimen collectors, group meeting facilitators, and worksite monitors); did not respond to potential relapses in a timely and adequate manner; and did not always require a physician to immediately stop practicing medicine after testing positive for alcohol or a nonprescribed or prohibited drug. Lastly, the Auditor found that MBC — which was charged with overseeing the diversion program — "has not provided consistently effective oversight."

Following receipt of the Auditor's Report, MBC — at its July 2007 meeting — unanimously voted to abolish the diversion program and to seek a repeal of the statutes creating the program. The program was abolished effective July 1, 2008. Thus, MBC has not had a program to monitor substance-abusing licensees for 15 years.

## Should MBC Wish to Create a New Program, It Must Comply "Without Deviation" With the Uniform Standards

Also, in 2008, the Legislature passed SB 1441 (Ridley-Thomas) (Chapter 548, Statutes of 2008), which added section 315 *et seq*. to the Business and Professions Code. Section 1 of SB 1441 succinctly stated the Legislature's unmistakable intent regarding the use of substance abuse monitoring programs by health care licensing boards:

<sup>&</sup>lt;sup>2</sup> Auditor General of California, <u>Review of the Board of Medical Quality Assurance</u> (No. P-035) (August 1982); Auditor General of California, <u>The State's Diversion Programs Do Not Adequately Protect the Public from Health Professionals Who Suffer from Alcoholism or Drug Abuse</u> (No. P-425) (January 1985); Auditor General of California, <u>The Board of Medical Quality Assurance Has Made Progress in Improving its Diversion Program; Some Problems Remain</u> (No. P-576) (June 1986).

> (a) Substance abuse is an increasing problem in the health care professions, where the impairment of a health care practitioner for even one moment can mean irreparable harm to a patient. ... (c) Substance abuse monitoring programs, particularly for health care professionals, must operate with the highest level of integrity and consistency. Patient protection is paramount. (d) The diversion program of the Medical Board of California, created in 1981, has been subject to five external audits in its 27-year history and has failed all five audits, which uniformly concluded that the program has inadequately monitored substance-abusing physicians and has failed to promptly terminate from the program, and appropriately refer for discipline, physicians who do not comply with the terms and conditions of the program, thus placing patients at risk of harm. (e) The medical board's diversion program has failed to protect patients from substance-abusing physicians, and the medical board has properly decided to cease administering the program effective June 30, 2008. ... (g) Various health care licensing boards have inconsistent or nonexistent standards that guide the way they deal with substance-abusing licensees. (h) Patients would be better protected from substance-abusing licensees if their regulatory boards agreed to and enforced consistent and uniform standards and best practices in dealing with substance-abusing licensees.

SB 1441 required DCA to convene a "Substance Abuse Coordination Committee" (SACC) to develop "uniform and consistent standards" in 16 specified areas that "each healing arts board shall use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program." Bus. & Profs. Code section 315(c) (emphasis added). DCA convened the SACC in 2010, and — following extensive public hearings — it released the original version of the "Uniform Standards Regarding Substance-Abusing Healing Arts Licensees" (Uniform Standards) in 2011. The current 2019 version of the Uniform Standards is available on DCA's website.

SB 1177 (Galgiani) (Chapter 591, Statutes of 2016) added new section 2340 *et seq*. to the Business and Professions Code, which authorizes MBC to create a new monitoring program for substance-abusing licensees. SB 1177 echoed SB 1441's mandated use of the Uniform Standards by providing that "if the board establishes a program, the program *shall* ... *comply* with the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees as adopted by the Substance Abuse Coordination Committee of the department pursuant to Section 315." Bus. & Profs. Code section 2340.2(e) (emphasis added).

Additionally, the Board's own regulations that it adopted following the development of the Uniform Standards confirm its intention that the Uniform Standards "shall" be used "without deviation, for each individual determined to be a substance-abusing licensee." Section 1361, Title 16 of the California Code of Regulations.

Thus, the mandatory use of the Uniform Standards by any new program created by MBC cannot be questioned. Indeed, it is MBC's burden to ensure that the language of these proposed

regulations (and any subsequent regulations affecting the proposed PHWP) is absolutely consistent with the Uniform Standards. Failure to do so in this rulemaking proceeding being conducted pursuant to the Administrative Procedure Act (APA), Gov't Code section 11340 *et seq.*, requires rejection of the proposed regulations under the "consistency" standard set forth in Government Code sections 11349 and 11349.1. Furthermore, failure to ensure that the language of these proposed regulations is clear and unambiguously consistent with the Uniform Standards would require rejection of the proposed regulations under the "clarity" standard set forth in those same provisions of the APA.

CPPC recounts this history and these facts because no current member of the Medical Board (the decisionmakers in this rulemaking proceeding) was on the Board during 2004–05 when the Enforcement Monitor issued her reports, or in 2007 when the State Auditor issued her follow-up report, or in July 2007 when MBC voted unanimously to abolish the program. Only three current MBC members were on the Board when SB 1177 was passed in 2016, and when the Board voted to implement SB 1177 in January 2017. The current Board may wish to revisit that decision. Thus, it is important to educate the relevant decisionmakers about the history of MBC's experience with a program purporting to monitor substance-abusing physicians, and with the law now applicable to the operation of such a program. MBC must learn from its past mistakes in operating such a program; as the saying goes, those who ignore history are doomed to repeat it. Any such repetition would cause irreparable harm to patients.

It bears emphasis that the program proposed by this rulemaking is a program of the Medical Board of California. The highest priority of the Medical Board of California is patient protection; when patient protection is inconsistent with some other interest sought to be promoted, patient protection is paramount.<sup>3</sup> This kind of program has been proven on five separate occasions to pose grave risk to patients instead of protecting them. MBC is prohibited from creating a new program that will violate its highest priority; additionally, it is prohibited from creating a new program that is in any way inconsistent with the Uniform Standards. Any such deviation is barred by the Board's own regulations (section 1361, Title 16 of the California Code of Regulations), and by the explicit language of SB 1441 (Bus. & Profs. Code section 315(c)) and SB 1177 (Bus. & Profs. Code section 2340.2(e)).

### **Inconsistencies with the Uniform Standards**

CPPC's primary argument is that the proposed regulations (like the bill that the regulations purport to implement) appear to carve out a distinction between the way so-called "self-referrals" and "Board-referrals" can or should be treated. Specifically, some of the proposed regulations imply that self-referred participants are not fully subject to the Uniform Standards. As discussed above, nothing in the Uniform Standards makes that distinction. In fact, to our knowledge, the term "self-referrals" is used only once in the 29-page Uniform Standards (Standard #14).

<sup>&</sup>lt;sup>3</sup> Business and Professions Code sections 2001.1, 2229(a) and (c).

The mandatory use of the Uniform Standards by <u>all</u> DCA healing arts boards in dealing with <u>all</u> substance-abusing licensees participating in substance-abuse monitoring programs is unambiguously clear in two statutes (Business and Professions Code sections 315 and 2340.2 (e)), and existing Board regulation (section 1361, Title 16 of the CCR), and in the Uniform Standards themselves. None of those provisions draw any distinction between self-referred participants and Board-referred participants, and any attempt to do so in these proposed regulations should be rejected.<sup>4</sup> Alternatively, MBC could cure this problem by modifying these proposed regulations to declare that nothing in them is intended to justify any difference in how self-referred and Board-referred participants are to be treated by the PHWP.

Below, CPPC identifies areas in which the proposed regulations conflict with the Uniform Standards. These inconsistencies violate the "consistency" requirement of Government Code sections 11349 and 11349.1. In addition, the language of some of the proposed regulations is so confusing that it is impossible to tell whether they are consistent with the Uniform Standards. These inconsistencies violate both the "clarity" and "consistency" requirements of Government Code sections 11349 and 11349.1. Additionally, some of the proposed regulations duplicate regulatory provisions that MBC has already adopted in a prior rulemaking proceeding — something that adds to the confusion and is prohibited by the APA's "nonduplication" standard. Finally, the PHWP's enabling statute does not authorize at least one provision.

1. <u>Clinical Diagnostic Evaluation (CDE)</u>. Uniform Standard #1 requires all program participants to undergo a CDE. Uniform Standard #2 (1) requires all program participants to cease practicing medicine pending the results of the CDE, (2) requires all program participants to undergo twice-weekly drug testing during the cease practice period, and (3) prohibits any return to practice until the participant has demonstrated 30 days of negative drug tests. Uniform Standards #1 and #2 make no distinction between self-referred participants and Board-referred participants.

An existing Board regulation (section 1361.5(c), Title 16 of the CCR) already specifies the CDE requirements of Uniform Standard #1 applicable to a Board-referred participant (in other words, a participant whose license is on probation, one term of which is required participation in the PHWP). Proposed section 1357.10(c) is arguably duplicative of section 1361.5(c), in violation of Government Code sections 11349(f) and 11349.1(a). More importantly, proposed section 1357.10(c) implies that a CDE is optional for a self-referred participant ("If the vendor ... requires a participant to undergo a clinical diagnostic evaluation...") when no such option exists in Uniform Standard #1, raising consistency and clarity issues. See also proposed section 1357.10(h)(1), which also implies that the CDE is optional. Proposed sections 1357.10(c) and 1357.10(h)(1)

<sup>1</sup> 

<sup>&</sup>lt;sup>4</sup> Critically, so-called "self-referred" participants are often attempting to enter a monitoring program in order to beat a piece of information that they know is imminently arriving at MBC, *e.g.*, a DUI arrest, a hospital disciplinary action reported to MBC under Business and Professions Code section 805, and/or a complaint. In the past, physicians attempted to "self-refer" because that status conferred benefits under now-repealed provisions of the Business and Professions Code. Under the Uniform Standards, self-referred participants are not entitled to special or different treatment.

must be clarified to require the vendor to comply with Uniform Standards #1 and #2 for all participants.

2. <u>Communication with Employers of Participants.</u> Uniform Standard #3 concerns the ability of a DCA healing arts board to communicate with a program participant's employer or supervisor — say, for example, concerning a positive drug test. It requires a licensee who is in a diversion program to provide to the board contact information on all employers and supervisors, and to give specific, written consent that the licensee authorizes the board and the employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring. Uniform Standard #3 makes no distinction between self-referred participants and Board-referred participants.

Proposed section 1357.10(d) also concerns communication between the PWHP and a participant's employer or supervisor. As to Board-referred participants, proposed section 1357.10(d) is duplicative of existing Board regulation 1361.5(c)(2), Title 16 of the CCR. And nothing in proposed section 1357.10(d) requires a vendor to require a self-referred participant to permit communication between the PWHP and the participant's employer or supervisor. Although proposed section 1357(e) requires PWHP participants to provide "disclosure authorizations," the inconsistency between these two sections illustrates a lack of clarity that may permit a future vendor to treat self-referred participants differently from board-referred participants.

- 3. Other Provisions That Appear to Draw an Impermissible Distinction Between Self-Referred and Board-Referred Participants. Several other regulations proposed in this package suffer from the same issue a confusing and unclear effort to permit self-referred participants to be treated differently from Board-referred participants, which is not permitted by or contemplated in the Uniform Standards. Staff should re-examine proposed sections 1357.10(e)(2), 1357.10(g), 1357.10(j), 1357.10(k), and 1357.10(l).
- 4. No Statute Authorizes the Vendor to Impose Restrictions on a Participant's Medical Practice. Proposed section 1357.11 assumes that the PHWP vendor is authorized to impose restrictions on a program participant's medical practice ("if a vendor imposes a practice restriction on a participant..."). It prescribes reporting and disclosure requirements concerning such restrictions. CPPC can find no provision in SB 1177 (Galgiani) that authorizes the program vendor to impose any practice restrictions. Under the statute, the vendor is required to report noncompliance, program withdrawal, and/or program termination to the Board (all subject to strict confidentiality provisions). Still, nothing authorizes the vendor to restrict a physician's medical practice. Only MBC can do that. This regulation must be rejected for lack of authority under Government Code sections 11349 and 11349.1.
- 5. These Regulations Should Establish a Standing Board Committee to Oversee the PHWP. As documented above, five prior audits of MBC's former diversion program uniformly found it failed to protect patients from substance-abusing licensees due in large part to the Board's failure to exercise any meaningful oversight over the program. Should this Board

decide to implement SB 1177 by creating a new PHWP, it must also create a mechanism by which Board members actively supervise the functioning of the program.

### **CONCLUSION**

A proper analysis of these proposed regulations requires a detailed focus on the language and intent behind SB 1441 (Ridley-Thomas), SB 1177 (Galgiani), and the Uniform Standards-related rulemaking already conducted by the Board — a daunting task. It also requires a simpler exercise. MBC's statutory priority is public protection. As noted above, that priority is reflected in three different statutes. Further, "where rehabilitation and protection are inconsistent, protection is paramount." Business and Professions Code section 2229(c). When MBC seeks to create a rehabilitation program, it is the Board's burden to ensure that patients are protected above all else. The Board must reject these proposed regulations as unclear, inconsistent with two statutes and the Uniform Standards, duplicative of other Board regulations, and unauthorized.

Sincerely,

Marcus Friedman

Administrative Director

**Consumer Protection Policy Center** 

Maraya Fruit

Cc: Randy W. Hawkins, M.D., President, Medical Board of California

Reji Varghese, Executive Director, Medical Board of California

Senator Richard Roth, Chair, Senate Business, Professions & Economic Development Committee

Assemblymember Marc Berman, Chair, Assembly Business & Professions Committee Kimberly Kirchmeyer, Director, California Department of Consumer Affairs

From: Kim Andosca

To: Schembra, Alexandria@MBC

Subject: CSAM Comments

**Date:** Tuesday, November 14, 2023 4:11:06 PM

Attachments: <u>image001.jpg</u>

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November 14, 2023

Alexandria Schembra Medical Board of California 2005 Evergreen St., Ste. 1200 Sacramento, CA 95815

RE: Physician and Surgeon Health and Wellness Program -Comments

The California Society of Addiction Medicine (CSAM) is the professional organization representing physicians who treat Substance Use Disorders (SUD's) here in California.

As the experts in this field, we are writing to provide comment on the proposed regulations for the Physician and Surgeon Wellness Program. We appreciate the Medical Board of California (MBC)'s efforts to recreate a program to ensure physicians who suffer from SUD's and other mental health issues get the help needed. Our goal has always been to help physicians obtain evidenced-based care for their illness while at the same time creating guidelines and safeguards to protect patients.

With that forefront in our minds, we have several points of concern about the proposed regulations that need consideration as you move forward.

**Program Title.** Change or clarify that the program only handles substance use disorder and does not treat or address mental health conditions. The title implies, in our opinion, many other potential health/wellness conditions.

**Vendors.** Vendors who will be contracted need to be chosen in a transparent way so that there are uniform standards in place. Treatment goals and expected outcomes need to be consistent across the vendors. Operations, ideology, and routine practices should be open to examination.

**Costs**. We suggest that the board waive cost recovery for physicians who successfully complete the program. This may not incentivize use of the program since it would be a condition of probation, but it would lower the barrier to reentry to normal practice for physicians who have taken meaningful steps towards recovery.

**Program Review**. The MBC should establish a mechanism for regular periodic review by subject matter expert professionals in the field for the purpose of sending information and recommendations to the MBC regarding the programs effectiveness.

**Audit.** Regular audits and outcome studies should not be vendor financed, but rather be state-budgeted and should be RFP's for UC medical university research groups.

Disclosure. Add language to section 1357.9 requiring participants be notified when a request for their records is received.

Again, as experts in these issues, we invite the Board to reach out to us at anytime to assist with the important implementation of this program.

Sincerely,

Randolph P. Holmes, MD FAAFP DFASAM, CSAM Government Affairs Chair cc CSAM Board of Directors From: Stefanie Simmons
To: Regulations, MBC@MBC

Cc: Corey Feist

Subject: Physician and Surgeon Health and Wellness Program

Date: Tuesday, November 14, 2023 10:21:56 AM

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To the Medical Board of California,

I applaud the consideration of a physician monitoring program in California. I am writing today to offer substantial concern about the program as currently described. Although designated a Health and Wellness Program, this program seems to consist solely of substance use monitoring. A best practice program for the protection of clinicians AND patients (who benefit from clinicians who receive physical and mental health care) includes the following:

- 1. Confidentiality from the board of medicine unless patient safety is at risk.
- 2. Proactive treatment for all potentially impairing conditions, not just substance use disorders.
- 3. Clear communication of the costs and limits of confidentiality in the program.
- 4. Inclusion of licensed health workers beyond physicians.

The current program, as written, does not provide these key areas of impact on the wellbeing of clinicians and patients. Please consider a different model of providing this essential service.

With great regard, Stef Simmons, MD

--

Dr. Stefanie Simmons (she/her) Dr. Lorna Breen Heroes' Foundation Chief Medical Officer https://drlornabreen.org/ From: Marian Hollingsworth

To: Regulations, MBC@MBC

**Subject:** Testimony for MBC Hearing on Physician and Surgeon Health and Wellness Program

**Date:** Tuesday, November 14, 2023 12:46:17 PM

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To Whom It May Concern:

I would like to submit my testimony regarding the Physician and Surgeon Health and Wellness Program that I have this morning at the Medical Board's Public Hearing on this subject.

Thank you for your time, Marian Hollingsworth Patient Safety Advocate

Good morning. My name is Marian Hollingsworth and I am a patient safety advocate with an opinion of the Physician and Surgeon Health and Wellness Program.

First, while I think that doctors with addictions should get help, I think it's a conflict of interest for the Medical Board to be involved — and to put those doctors first over the safety of consumers. SB 1177 claims it's the Board's purpose to maintain the integrity of the medical profession. This is wrong because the Board's own mission statement says its primary purpose is to PROTECT CONSUMERS THROUGH THE LICENSING AND REGULATION OF PHYSICIANS. Nowhere does the mission statement say the Board is to maintain the integrity of the profession. By saying that, SB 1177 puts the Board on the side of the doctors — over the safety of consumers.

Other concerns are that the Board's involvement in the Physician and Surgeon Health and Wellness Program creates a conflict of interest, particularly since doctors will be paying the Board a fee yet to be determined under B&P code 2340.8.

Also, under 1357.13 #9, this Program is to report the number of patients who have been harmed or killed by participants every year so that the board can include those figures in its Annual Report. Are you expecting a number of harmed and dead patients every year? The fact that you expect harmed patients from participants in this program is appalling.

1357.14 states that the program will be audited every 3 years. It won't identify participants by name, but will identify non compliance or deficiencies that would interfere with the Board's "mandate of public protection." So, how will you know which participant is non-compliant in order to protect the public?

This Physician Health and Wellness Program fails to follow the Uniform Standards which are state law. The Board should review the Uniform Standards before embracing this program. I

agree with the inconsistencies the CPPC outlined earlier.

Finally, there is the matter of doctor confidentiality versus the patients' right for full informed consent. Doctors are supposed to talk to their patients about all the risks and benefits of any treatment or procedure. Yet the risk of an addicted doctor is expected to remain a secret? I have spoken to a number of people about whether they would want to know if their doctor was in a drug diversion or rehabilitation program. EVERY SINGLE PERSON I ASKED SAID THEY WOULD WANT TO KNOW.

It flies in the face of the Board's own mission statement to deny patients the right to know about the safety of their own doctor so they can make their own healthcare decisions.

Nothing is stopping impaired doctors from seeking treatment elsewhere. So the argument that the poor doctors need this Wellness Program isn't credible because there are plenty of rehab programs to choose from. It isn't the Board's responsibility to take care of them.

I implore this Board to make changes in the Physician and Surgeon Health and Wellness Program to protect consumers – and maintain their right to full informed consent for their healthcare decisions by not making it confidential.

Thank you.

# CALIFORNIA MEDICAL ASSOCIATION

November 14, 2023

Alexandria Schembra Medical Board of California 2005 Evergreen St., Ste. 1200 Sacramento, CA 95815

Sent via email to regulations@mbc.ca.gov

Dear Ms. Schembra:

On behalf of the California Medical Association (CMA) and our nearly 50,000 physician and medical student members, CMA writes to respectfully request amendments to the proposed regulations implementing the statute adopted by SB 1177 (Galgiani, 2016)

Program Title Concerns

CMA sponsored SB 1177 to establish a Physician and Surgeon Health and Wellness Program (PHWP) in 2016 because California medical doctors are the only licensed health care professionals without a wellness and treatment program aimed at providing support and rehabilitation for substance abuse. Further, California is just one of a few states nationwide that does not provide a pathway for physicians and surgeons to address substance abuse and mental health problems. Most states have robust physician health programs to evaluate and coordinate care for physicians suffering from mental health, behavioral health, or substance abuse issues. Because there is no program in California, many who suffer from these conditions often do not know where to turn for help.

As SB 1177 moved through the legislature, language allowing the Medical Board of California (MBC) to offer services supporting physicians suffering physical or mental health problems and burnout was removed from the bill, but the title Physician and Surgeon Health and Wellness Program remained. CMA recommends changing the name of the program to the "Physician and Surgeon Health Program" to avoid the potential for physicians to assume the program offers mental health treatment and guidance as the term "wellness" is associated within the medical community with improving one's mental health.

Recognizing that the name "Physician and Surgeon's Health and Wellness Program" is in the authorizing statute, if it is not possible to change the name of the program, CMA asks that the board add a requirement that all points of entry to the program, such as the website or vendor phone line, contain a disclaimer clarifying the program only addresses substance use disorder and a redirection to appropriate resources.

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cmadocs.org

To this end, CMA proposes the following addition in bold be made:

§1357.10(a) – The vendor shall comply with and is responsible for ensuring that all contractors and subcontractors comply with the Board's requirements contained in Article 14 of the Code and this article. In addition, the vendor is obligated to comply with and bears responsibility for ensuring that all contractors and subcontractors adhere to the requirement of posting clear disclaimers at every participant entry point, including but not limited to the program website, call center interactions, and associated materials. The prescribed disclaimer must explicitly communicate that the program is exclusively dedicated to addressing substance use disorders among physicians and surgeons.

High Cost of Participation

In its initial statement of reasons, the MBC estimates that a licensee participating in the PHWP for five years will incur approximately \$137,104 in program costs or \$212,687 in program costs and income loss if inpatient treatment is required. This high cost will likely discourage some physicians from self-referral, creating a barrier to early intervention which is much more closely aligned to consumer protection than erecting insurmountable barriers to care that allow treatable impairment to continue. The Board's ability to refer as part of discipline is the most likely path to participation.

Since the Medical Board of California remains one of the few healing arts boards that is not authorized to refer licensees to a program in lieu of discipline, CMA believes the MBC should consider other options to lower barriers to return to a license in good standing for physicians referred to the program as part of the disciplinary process who successfully complete the program. According to the National Institute of Mental Health, substance use disorder is a **treatable** mental disorder. The overlay of the costs associated with both the PHWP and cost recovery is inappropriately punitive for discipline that is associated with care for a health condition.

CMA requests that any remaining cost recovery assignment be waived, and cost recovery expenses already paid be reimbursed when a Board-referred physician successfully completes the program as a condition of probation.

CMA's proposed language is as follows in bold:

§1357.1(h) The <u>participant</u> agrees in writing to cooperate with all elements of the diversion agreement for admission into the program, including all sections of this article, and to pay all costs required for participation in the program. Cost recovery amounts assigned to board-mandated participants disciplined for substance

<sup>&</sup>lt;sup>1</sup> National Institute of Mental Healht, Substance Use and Co-Occurring Mental Disorders. Accessed at <a href="https://www.nimh.nih.gov/health/topics/substance-use-and-mental-health">https://www.nimh.nih.gov/health/topics/substance-use-and-mental-health</a>

abuse problems shall be expunged upon successful program completion.

Payments to cost recovery assignments already made by the participant who successfully completes the program shall be reimbursed.

### Audit Information

CMA requests that audit reports be available to participants upon request, promoting transparency within the program. Furthermore, the provision for privacy-compliant redacted audit reports to be made available to the public upon request enhances public accountability and trust. As a result, CMA requests that the following subsection be added to Section 1357.14:

§1357.14(f) The audit reports referenced in this section shall be provided to the participant upon request. Also, privacy law-compliant redacted audit reports may be made available to the public upon request.

Records Request Transparency

Confidentiality is a cornerstone of physician health programs across the country. The statute gives the Board the ability to receive certain information about participants in certain circumstances. CMA asks that participants at least be notified by the program whenever their records have been shared with the board. CMA's proposed language should be added as follows:

# §1357.12(e) A participant shall be notified by the program when it shares their records with the board.

### Clarifying Definitions

CMA believes the following subsection should be deleted to avoid confusion as conflicts of interest involving participants are not referenced in the regulations:

§1357(c) "Conflict of Interest" means having a financial, personal, or familial relationship with the participant, or other relationship that could reasonably be expected to compromise the ability of the other to render impartial and unbiased reports.

Further, conflicts of interest are only addressed in Section 1357.14(a) which concerns conflicts of interest between the program vendor and auditor and the definition for conflict of interest is included within this language. CMA requests that this language be amended to include professional conflicts of interest, so that it reads as follows:

§1357.14(a) At least once every three (3) years, and at any other time requested by the Board with at least 90 days' notice from the Board, an external, independent audit shall be conducted by a qualified reviewer or review team from outside the Department of Consumer Affairs with no conflict of interest with the vendor (i.e., no reviewer or individual on a review team has a current or prior business, **professional**, personal, or financial relationship with the

vendor or any employee or officer of the vendor) providing the monitoring services. In addition, the reviewer shall not be a part of or under the control of the Board. The independent reviewer or review team must consist of licensed certified public accountant(s) or public accountant(s) who have at least five (5) years' experience in the professional practice of internal auditing and assessment processes and are qualified to perform audits of monitoring programs. The cost of the audits shall be borne by the vendor and factored into each participant's fee.

Thank you for your consideration of this request. SB 1177 was an important first step in rectifying the void that exists in California's patient protection landscape because the MBC does not have a physician health program. Similarly, it is important that work continue to ensure that the program aligns with well-established best practices for physician health and wellness programs, much of which goes beyond what can be done under the current authorizing statute. CMA looks forward to continuing to work with the MBC to achieve a program that aligns with best practices for physician health programs and appreciates your consideration of our requested amendments to the proposed regulations.

If you have additional questions, please contact me at <a href="mailto:levensen@cmadocs.org">levensen@cmadocs.org</a>.

Sincerely,

Lucas Evensen

Associate Director, Strategic Engagement

California Medical Association

Lucas Evensen





November 14, 2023

Alexandria Schembra Medical Board of California 2005 Evergreen Street, Suite 1200 Sacramento, CA 95814

Proposed Regulatory Action Concerning Physician and Surgeon Health and Wellness Program -Re: **Reestablishing the Diversion Program** 

Dear Ms. Schembra,

On behalf of the California State Association of Psychiatrists (CSAP), I write to you in opposition, unless amended, to the proposed regulations to reestablish the diversion program of the Medical Board of California (MBC). The proposed regulations may establish an anti-therapeutic program, which would unnecessarily harm physicians being treated and interfere with proper mental health care, including for substance use disorder. It is CSAP's hope that your Board can work with California's physicians and the Legislature on a different paradigm that would – as it the case in several other states – have as its focus physician health thereby contributing to patient care. Until then, CSAP suggests that you act on the suggestions of the California Medical Association and others that are to some extent echoed herein.

CSAP must respectfully oppose these regulations because the new diversion program will interfere with appropriate treatment and unfairly stigmatize and destroy the careers of physicians who are in recovery as well as interfere with diagnosis and treatment by specialists in addiction, including psychiatrists. Specifically, there are concerns with the title of the program, the "Physician and Surgeon's Health and Wellness Program," and CSAP suggests that, if possible, it should be changed or a disclaimer should be added, in order to clarify that the program only handles substance use disorder and does not treat or address mental health conditions.

To this end, CSAP proposes the following addition in bold be made:

§1357.10(a) – The vendor shall comply with and is responsible for ensuring that all contractors and subcontractors comply with the Board's requirements contained in Article 14 of the Code and this article. In addition, the vendor is obligated to comply with and bears responsibility for ensuring that all contractors and subcontractors adhere to the requirement of posting clear disclaimers at every participant entry point, including but not limited to the program website, call center interactions, and associated materials. The prescribed disclaimer must explicitly communicate that the program is exclusively dedicated to addressing substance use disorders among physicians and surgeons.

CSAP also has concerns over the costs that will be incurred for physicians required to participate in the program as a result of discipline. In its initial statement of reasons, the MBC estimates that a licensee participating in the "Physician and Surgeon's Health and Wellness Program" for five years will incur approximately \$137,104 in program costs or \$212,687 in program costs and income loss if inpatient treatment is required. This high cost will likely discourage some physicians from self-referral, creating a barrier to early intervention which is much more closely aligned to consumer protection than erecting insurmountable barriers to care that allow treatable impairment to continue. This is why CSAP suggests that the regulations should incorporate a proposal that would allow the Board to waive cost recovery, and for cost recovery expenses already paid to be reimbursed for physicians who successfully complete the program as a condition of probation. While CSAP acknowledges that this may not incentivize the use of the program, since it would be a condition of probation, it would lower the barrier to reentry to normal practice for physicians who have taken meaningful steps towards recovery.

A way to amend this satisfactorily would be as follows:

§1357.1(h) The <u>participant</u> agrees in writing to cooperate with all elements of the <u>diversion</u> agreement for admission into the program, including all sections of this article, and to pay all costs required for <u>participation</u> in the program. <u>Cost recovery amounts assigned to board-mandated participants</u> <u>disciplined for substance abuse problems shall be expunged upon successful program completion.</u>

Payments to cost recovery assignments already made by the participant who successfully completes the program shall be reimbursed.

CSAP also has further questions about the language of the proposed regulations. For example, CSAP would like more clarification pertaining to the circumstances and the limit of the authority of the vendor when it comes to imposing practice restrictions. CSAP also would like more information on the way section §1357.9 is phrased regarding record retention. Particularly CSAP would like to know if this information would be subject to disclosure with a Public Records Act request. Lastly, CSAP suggests the Board add language to section 1357.14, to require audits to be available to the public and participants in the program, and that the Board should also add language to section 1357.9 requiring participants to be notified when it receives a request for their records. As a result, CSAP requests that the following subsections be added to Sections 1357.14 and 1357.9:

§1357.14(f) The audit reports referenced in this section shall be provided to the participant upon request. Also, privacy law-compliant redacted audit reports may be made available to the public upon request.

§1357.9(g) A participant shall be notified by the program when it receives a request for the participant's records.

For these reasons, CSAP must respectfully oppose, unless amended, the proposed regulations for the Medical Board Diversion Program.

Sincerely,

Paul Yoder

Legislative Advocate

From: Linda Bresnahan

To: Regulations, MBC@MBC

Subject: RE: Public Comment Government Code section 11346.5 subdivision MBC Regulation Comment Period and Public Hearing November 14

**Date:** Tuesday, November 14, 2023 2:12:39 PM

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# Linda Bresnahan, MS Executive Director

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# 2024 FSPHP Annual Education Conference, April 17 – 21, 2024 Nashville,TN

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From: Linda Bresnahan

Sent: Tuesday, November 14, 2023 5:11 PM

To: regulations@mbc.ca.gov

Subject: Public Comment Government Code section 11346.5 subdivision MBC Regulation Comment Period and Public

Hearing November 14

Alexandria Schembra Medical Board of California 2005 Evergreen St., Ste. 1200 Sacramento, CA 95815 By email

#### FROM: The Federation of State Physician Health Programs

Please accept these comments submitted on behalf of the Federation of State Physician Health Programs. The Federation of State Physician Health Programs, Inc. (FSPHP) evolved from initiatives taken by the American Medical Association (AMA) and individual state physician health programs, focused on the need for the creation of confidential programs as an alternative to discipline that are dedicated to the rehabilitation and monitoring of physicians with

psychoactive substance use disorders as well as mental and physical illness. Currently, programs meeting the FSPHP State PHP criterion exist in 47 States, all but California, Nebraska, and Wisconsin.

The FSPHP is vested in seeing leading-edge practices put forth by State PHPs. These comments are submitted by Dr. Edwin Kim, on behalf of FSPHP. Dr. Kim is a board-certified addiction psychiatrist who serves as a medical director of Pennsylvania's Physician Health Program, director of Addiction Treatment Services at the Palo Alto VA health system, and as a Clinical Assistant Professor Affiliated with Stanford University. He is one of 15 FSPHP Board of Directors who lead Physician Health and Health Professional Programs across the US.

In accordance with Government Code section 11346.5 subdivision (a)(13), we implore members of the Board to consider a reasonable alternative to the proposed regulation concerning Physician and Surgeon Health and Wellness Programs as presented to you in written format here, accompanied by a copy of the FSPHP Physician Health Program Guidelines, and in verbal summary by Dr. Kim.

We want to acknowledge the eloquent change of language from a now-defunct impaired physician or diversion program to the newly minted Physician Health and Wellness Program signifies the board's and California's forward thinking in balancing the needs of protecting public safety and assisting physicians with a substance use disorder which is impairing or potentially impairing. The FSPHP considers the next natural step in this change of nomenclature to be the careful consideration that physician health programs not only assist in matters related to substance use disorders but also -- as seen in nearly all states with PHPs -- that programs are being asked to apply the proven PHP model -- in which the PHWP is rooted -- to other potentially impairing illnesses such as psychiatric disorders or even behavioral concerns. In essence, it is a matter of designing a program befitting to the excellent name.

We urge you to read carefully through these proposed alternatives submitted by the Federation of State Physician Health Programs as well as the organization's PHP Guidelines to consider reasonable amendments to the proposed regulation. This written comment brings to the Board's attention the leading-edge thoughts and recommendations by state PHPs with years of experience in protecting the public while concurrently promoting the health and well-being of their physicians.

The written submission outlines what is considered to be the most effective and least burdensome method to carry forth a state physician health program.

#### From this submission, we emphasize the following important points:

- Consider that individuals be permitted to seek assistance confidentially while also protecting the public. This CAN be accomplished and this truly is the RECOGNIZED way in which physicians can receive early intervention, and meaningful connection to care.
- Consider that with the transition to a newly minted HEALTH and WELLNESS PROGRAM that the Board and its proposed program CAN help protect public safety by expanding the scope of early intervention, connection to treatment, and monitoring... to conditions not strictly in the category of substance use disorders.
- Consider that PHPs are well-designed to assist with psychiatric disorders that are impairing or potentially impairing as well.
- Next, the costs for the program are largely projected onto the participant for evaluations, treatment, support groups, drug testing, and workplace monitor fees. The plan for \$168,000 for 5 years with all expenses to be paid by the participants is unfortunate and, in our opinion, underfunded. Furthermore, the struggling physician cannot be left to bear the weight of these substantial fees without assistance.
- Lastly, the anticipated 50 referrals annually with no plans for growth demonstrates a mistaken projection of prevalence. For a state with one of the highest number of actively licensed physicians, the penetrance of the proposed program is grossly underestimated considering the proportion of those who may be suffering.

Thank you for your time and consideration.

#### **Additional Comments**

• The Program includes the term "Wellness" while the purpose is strictly limited to those with a substance use or misuse related concern. Notably, current nomenclature suggests against the use of the term "abuse," and rather promotes updated language such as: individual with a substance misuse or use disorder, the presence of

a substance use disorder which is impairing or potentially impairing.

- Provisions for concerns related to mental health or psychiatric disorders better describe the proposed scope of a named "Wellness program". Nomenclature today in the space of physician health, wellness, and well-being is of the utmost importance. The program as it is named infers a physician can reach out to the Program for concerns related to mental health or psychiatric disorder assistance.
- State Physician Health Programs often work with individuals who are mandated for monitoring as well as those physicians who voluntarily seek assistance for an illness. The current proposed Program appears more aligned with a licensing board monitoring program for substance use disorders for those physicians who are mandated. In its current construct, there are limited reasons for physicians to come forward preventively for well-being or wellness. In other words, the early intervention component will be lacking.
- Excessive costs for each monitoring provision are projected directly on the participant (evaluation, treatment, support group, testing, and workplace monitor fees).
- The plan is for \$168000 for 5 years, with all expenses shouldered by the participants. This is unfortunate and underfunded.
- Revisit adequate funding such that the vendor provides support groups, and monitoring with the program funding, including evaluation and treatment resources that can have some opportunity for some insurance and workplace reimbursement for treatment of SUD medical conditions.
- There is a stated requirement to be out of work for 30 days with reference to this being "unpaid." Alternative language might include the use of medical leave of absence only when indicated and may be paid or unpaid depending on the individual's circumstance.
- The plan projects for severely underestimated penetration, to the extent that these numbers fall below thresholds for those likely with illness. There are an anticipated 40-50 referrals a year in your plan, with no plans for growth. This will not meet the needs of those predicted to be suffering from an illness.
- The estimated costs to participants for evaluation, treatment, drug testing, workplace monitoring, and group attendance listed do not contain any information about the fees that would be imposed by the monitoring vendor on the participants. Additionally, in the sections about the required 3-year external audits of the monitoring program, there is language that the costs of the audits will be paid by the monitoring vendor and those same costs can be factored into the monitoring fees of the participants of the program. The fees for which participants are responsible are too high to bear upon themselves.
- State Physician Health and Wellness Programs must consider methods to offset costs for residents, fellows, and unemployed physicians (many of these practitioners may be suffering from more severe health conditions including but not limited to co-occurring psychiatric and substance use disorders). This is an issue of inequity, likely will impact vulnerable/underserved populations more severely, and may result in continued loss of physician workforce in California. It behooves the Board and the Program to account for increased risk of physician suicide, which is exacerbated by loneliness and hopelessness. Financial burdens in the context of possible license action may severely impede physicians' ability to seek assistance.
- A novel Health and Wellness Program, with all that is known about Physician and Surgeon well-being, cannot ignore that healthcare workers are not only impaired or potentially impaired by substance use disorders. At minimum, the Board and Program must prevent inequitable or discriminatory attention towards individuals with substance use disorders. The should account for the undeniable prevalence of underlying mental health conditions or co-occurring disorders. Furthermore, the monitoring vendor should ensure the participant has access to and is engaged in treatment for these other conditions.

- Feedback and transparency are paramount in the realm of physician health. Include language about seeking monitoring participants' feedback as well as outlining the expected method by which the Board, the Program, the Vendor addresses complaints about the monitoring vendor. This should augment the proposed 3-year audits, and serve as a continuous platform for participants to provide confidential feedback both positive and negative, suggestions for improvement, privacy violations, and complaints about the monitoring vendor.
- Include language about how potential monitoring vendors will be selected/vetted.
- Outline requirements for the monitoring vendor to maintain policies and procedures for addressing informed consent, privacy, nondiscrimination, and a process for vetting complaints/appeals.
- Consider careful definitions of licensed supervision when determining drug testing frequency. Clarify who fits the role of "licensed supervisor" in the documentation that drug testing frequency can be reduced to 24 times yearly for those participants who have 50% supervision per day by a licensed supervisor. Further clarify the meaning of 50% supervision i.e. in treatment 50% of the time or working with a clinical/educational supervisor 50% in the workplace (as seen with medical trainees).
- Section 1357.12(d) states that if the CA Board initiates an investigation, the monitoring vendor has 3 days to notify the Board about whether the physician is in monitoring and compliance status. Clarify the circumstances in which non-compliance can be reported to prevent retaliatory or discriminatory reporting by the monitoring vendor. The Board and Program should consider thresholds for reporting which may include notifying participants which forms of non-compliance require reporting, and differentiating from those which do not. For example, non-payment of fees may be construed as non-compliant just as not attending groups or working with a workplace monitor as being non-compliant.
- Consider that most state PHPs are a resource for self-referring physicians who are seeking assistance for a substance use or psychiatric concern. The current proposal requires the monitoring vendor to report any positive drug testing to the Board indiscriminately. This opens an unnecessary and intrusive method of reporting a physician who has self-referred to the Program. Furthermore, to account for false positives, environmental contamination, or a medical reason that someone might test positive, when it is not a return to use, the language should read "confirmed" return to use. For example, poorly controlled diabetes can increase the risk of having a positive alcohol metabolite (EtG) in urine, not due to consumption of beverage alcohol. Reporting any positive will have huge impacts on willingness to self-refer and could be seen as discriminatory.
- The Board should reconsider the requirement for immediate cessation of practice for a single positive drug test, without any language about confirmation of return to use or concerns about current impairment. This could be considered discriminatory and a heavy-weighted approach which does not account for a state PHP's ability to help the Board and the participant navigate a positive test result. Mandating a physician to stop practice in the middle of the day, for someone who is otherwise doing well, compliant in monitoring, and likely not impaired, poses a risk for patient safety by preventing receipt of timely care. Consider updated language that the monitoring vendor will evaluate the positive test result with other data like testing history, workplace monitor reports, treatment provider reports, or in consultation with an evaluator or medical review officer before making a determination for ceasing practice.
- The currently proposed requirement for the monitoring vendor to report practice restrictions to the Board, and concurrent documentation on the public website indiscriminately includes both board-mandated participants and self-referred participants. This section should specify that practice restrictions imposed by vendor or treatment providers are due to the underlying health condition being monitored or impairment. It would be unreasonable that a participant that takes a leave of absence or is recommended for time away from work related to another non-impairing health issue or personal/family health issues will need to be reported. Reporting any restriction, especially in self-referred participants, will further limit participants to self-refer and could be seen as discriminatory.
- Consider that required reporting non-excused missed groups, even in self-referred participant to board within 2

business days resulting in disclosure of protected health condition can be inappropriate. This opens the possibility of a participant's information being exposed when they were merely tending to an emergent family or personal health issue. Consider amending the language to allow for monitoring vendor to confirm it was unexcused absence.

• Nail testing should be a provided option for testing as some participants cannot produce samples for hair testing due to any variety of physiological, social, cultural or religious reasons.

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#### **Additional Comments to specific sections:**

Title 16 of CCR (California Code of Regulations)

§ 1357.12. "(b) The vendor shall report in writing to the Board each minor violation by a participant. as defined in section 1361.52(c) within five (5) business days of the vendor's finding that the participant committed a minor violation, and shall identify the name and license number of the participant. and a detailed description of the violation(s), including the type and date of each occurrence."

**Comment:** This pertains to Uniform Standard #10, Specific consequences for major and minor violations. The reporting requirement for minor violations ensures that virtually 100% of self-referred participants will lose their confidential status with the Board, which will disincentive self-referrals and increase the likelihood that a licensee with a substance use disorder will not seek help.

**1361.5. Uniform Standards for Substance-Abusing Licensees**. Amendment only to section 1361.5, subdivision (c)(3) as follows:

- (3) **Biological Fluid Testing.**
- (A) The Board shall require biological fluid testing of substance-abusing licensees.
- (B) For the purposes of this section, the terms "biological fluid testing" and "testing" mean the acquisition and chemical analysis of a licensee's urine, blood, breath, or hair.
- (C) The Board may order a licensee to undergo a biological fluid test on any day, at any time, including weekends and holidays. Additionally, the licensee shall be subject to 52-104 random tests per year within the first year of probation, and 36-104 random tests per year during the second year of probation and for the duration of the probationary term, up to five (5) years. If there has been no positive biological fluid tests in the previous five (5) consecutive years of probation, testing may be reduced to one (1) time per month.

**Comment:** This corresponds to #4 Uniform Stand Frequency of Testing. This frequency of testing will benefit the lab and third-party vendors, because of increased revenue, however, there is no basis for this increased rate of testing frequency. 52-104 tests in the first year seems excessive and will decrease the likelihood of self-referrals. 24-36 tests in years 2-5 seems reasonable. Having an informed PHWP, with expertise commensurate with other state-voting members of the Federation of State Physician Health Programs, utilizing treatment recommendations from a treating entity with expertise in treating physicians (safety-sensitive workers) is the best way to guide decisions regarding testing frequency.

.....

BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standard #1 sets forth the requirements for clinical diagnostic evaluations for substance abusing licensees. The Board's regulations implementing the Uniform Standards became effective on July 1, 2015.

Additionally, BPC section 2340.2(d) requires the PHWP to provide for the confidential participation by a licensee who does not have a practice restriction based on substance abuse issues. Therefore, for individuals who self-refer into the PHWP and remain compliant, this proposed section ensures their confidentiality by clarifying that the references to the "Board" in existing regulation, 16 CCR section 1361.5(c)(1)(A)-(D), shall mean the vendor. Thus, a self-referred participant will only provide notice of their employers and consent to communicate to the vendor, and not the Board.

**Comment:** Describes confidentiality. This is good.

**Adopt 16 CCR section 1357.100)** Purpose: The purpose of proposed section 1357 .1 0G) is to indicate that if a participant is required to attend support group meetings, the requirements set forth under existing regulation, 16 CCR

section 1361.5(c)(4), shall apply. This proposed section also provides for the confidential participation by a licensee who does not have a practice restriction based on substance abuse issues.

Existing regulation, 16 CCR section 1361.5(c)(4), sets forth the criteria to determine the frequency of group meeting attendance and to verify that the meeting facilitators are experienced, objective, and licensed mental health professionals.

**Adopt 16 CCR section 1357.10(k)** Purpose: The purpose of proposed section 1357 .1 0(k) is to specify that if a participant is required to have a worksite monitor, the requirements set forth under existing regulation, 16 CCR section 1361.5(c)(5), shall apply.

Rationale: BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standard# 7 and #13(2)(c) set forth requirements for worksite monitors.

Under existing regulation, 16 CCR section 1361.5(c)(5), the worksite monitor must meet specified qualifications and must not have had a financial, personal, or familial relationship with the participant, but if it is impractical for anyone but the participant's employer to serve as the monitor, then this requirement may be waived by the Board, as appropriate.

This section prohibits employees of the participant from serving as their worksite monitor. Additionally, the worksite monitor must affirm that they have reviewed the terms and conditions of the participant's order and agree to monitor the participant as required. The worksite monitor must have face-to-face contact with the participant at least once a week, interview other staff in the office about the participant's behavior, if applicable, and review the participant's work attendance.

#### **Comment:** This seems very reasonable and is consistent with best practices.

### Adopt 16 CCR section 1357.10(1)

Purpose: The purpose of proposed section 1357 .10(1) is to ensure the participant meets the requirements set forth under existing regulation, 16 CCR section 1361.53, prior to returning to full-time or part-time practice. This proposed section also provides for the confidential participation by a licensee who does not have a practice restriction based on substance abuse issues.

Adopt 16 CCR section 1357.11

#### Adopt "Report and Public Disclosure of Practice Restrictions for Participants" as Title for 16 CCR section 1357.11

Purpose: The purpose of adopting 16 CCR section 1357.11 is to set out reporting requirements for program vendors and give participants notice regarding public disclosure of practice restrictions in a regulation section with a clear title. Add section 1357(i) Practice restriction definition. "means a restriction from practicing medicine for any period of time or limiting the number of hours the participant can practice medicine; the locations where the participant can practice; or the types of services or procedures they may perform. The PHWP may impose practice restrictions on the participant, and under BPC 2027(a)(3)(C), practice restrictions must be reported to the Board and posted on the licensee's profile." P. 7/46

Comment: See next Recommended adoption comment.

#### **Adopt 16 CCR section 1357.11** (p.28/46)

Purpose: The purpose of proposed section 1357 .11 is to require the vendor to report a participant's practice restriction to the Board and require the Board to post the practice restriction on the participant's profile on the Board's website. If the participant selfreferred to the PHWP, then the public disclosure will not indicate that the status is the result of enrollment in the program. Further, this proposed section provides for timely notification of the vendor to report a participant's practice restriction within one business day of imposition and requires the Board to remove the practice restriction from the participant's profile within one business day of being notified that the practice restriction has been lifted.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties by providing for transparency and ensuring that the public is notified timely if a participant has a practice restriction, regardless of whether the participant is Board-referred or self-referred, consistent with Uniform Standard #14. This proposed section also benefits interested parties by requiring the Board to remove the posting of the practice restriction within one business day of being notified it has been lifted.

Rationale: BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. This proposed section complies with Uniform Standard #14. Specifically, pursuant to Uniform Standard #14, the vendor is required to notify the Board of the participant's name; whether the participant's license is restricted or in a non-practice status; and a detailed description of each restriction imposed. The vendor will be required to make this report to the Board within

one business day of imposing a practice restriction on a participant, regardless of whether the participant is Board-referred or self-referred so that the Board may alert the public to the practice restriction. Such timely notification is necessary for consumer protection. To protect the privacy of a selfreferred participant, however, the Board will not indicate that the practice restriction has been imposed by the PHWP.

**Comment:** Every licensee with a moderate or severe substance use disorder (SUD) diagnosis will likely require residential SUD treatment, requiring cessation of practice. The mandated reporting to Med Board and public posting will further stigmatize addiction and disincentivize self-referrals to PHWP. ANY DECREASE in referrals will contribute to higher likelihood of a licensee practicing with an untreated potentially impairing illness.

#### Adopt 16 CCR section 1357.12(b)

Purpose: The purpose of proposed section 1357.12(b) is to require the vendor to report participants' minor violations, as defined in existing regulation 16 CCR section 1361.52(c), in writing to the Board within five business days of finding that the participant committed a minor violation, along with the licensee's name, license number, and a detailed description of the violation.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties by ensuring the Board is notified in a timely manner about a participant's minor violation of the program requirements. Timely notification of a minor violation will allow the Board to investigate the matter and take enforcement action as warranted. Such reporting mandates also serve as an incentive to participants to comply with the program requirements.

**Comment:** The reporting requirement for minor violations ensures that virtually 100% of self-referred participants will lose their confidential status with the Board, which will disincentive self-referrals, and increase the likelihood that a licensee with a substance use disorder will not seek help. All of the other reporting requirements seem reasonable to me.

#### Amend 16 CCR section 1361.5(c)(3) (p.41/46)

Purpose: The purpose of the proposed amendments to section 1361.5(c)(3)(G) is to implement changes to the Uniform Standards relating to biological fluid testing adopted by the SACC and made effective as of March 2019. These amendments indicate that licensees subject to biological fluid testing require Board approval for any changes to testing frequency and any alternative testing schedule and testing locations.

Anticipated Benefits: The Board anticipates that this amendment will provide clarity to interested parties that prior Board approval is required for changes to testing frequency and alternative testing schedules and locations. Further, this amendment will make the Board's regulations implementing the Uniform Standards consistent with the Uniform Standards adopted by the SACC, effective March 2019.

Rationale: This proposed amendment is necessary to update the Board's Uniform Standards relating to biological fluid testing under section 1361.5(c)(3)(G) to be consistent with modifications the SACC made to Uniform Standard #4, effective March 2019. Existing law indicates that prior to changing testing locations for any reason, alternative testing locations must be approved by the Board. This section does not allow for an alternative testing frequency, however, which creates problems for licensees who are traveling, but who are subject to being required to test on any day, including while traveling outside of California or the country. Current law can risk an otherwise compliant licensee becoming non-compliant with the terms of their probation, because of their travel schedule and the wording of existing law.

Consequently, the proposed amendment modifies section 1361.5(c)(3)(G) to indicate that prior to changing the testing frequency for any reason, including during vacation or other travel, any alternative testing schedule and testing locations must be approved by the Board. This allows the Board flexibility to alter the testing frequency and locations to accommodate vacation and other travel, if approved, without putting the public at risk, as the Board can require the licensee to submit to a test on any day, including upon the licensee's return from travel.

#### **Comment:** See #4 Uniform Standard, below.

### Add 16 CCR section 1361.5( c)(3)(I)(6) (p.42/46)

Purpose: The purpose of this proposal is to implement changes to the Uniform Standards relating to biological fluid testing adopted by the SACC and made effective as of March 2019, by amending section 1361.5(c)(3)(I) to add subdivision (6) to provide for a new exception to the biological fluid testing frequency schedule. This proposal would allow the Board to reduce testing frequency to a minimum of 24 times per year for a practicing licensee who receives a minimum of 50 percent supervision per day by a supervisor licensed by the Board.

Anticipated Benefits: This proposed addition will make the Board's regulations implementing the Uniform Standards consistent with the Uniform Standards adopted by the SACC, effective March 2019, and will provide for an additional

exception to the biological fluid testing frequency schedule for those practicing individuals being supervised at least 50 percent per day by a supervisor licensed by the Board.

**Comment:** What is "being supervised at least 50% per day by a supervisor licensed by the Board"

**Cost Impact** on Representative Private Person or Business: (p.44/46)

These costs will apply to licensees subject to discipline by the Board as a substance abusing licensee, or who self-refer into the PHWP.

"...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."

Out of these 40 probationers each year, approximately eight participants will be required to undergo a 30-day intreatment program and may be subject to lost wages during this time.

**Comment:** In Mississippi, and other states, PHPs will monitor 1-2% of actively practicing physicians in the state. Considering California has more active physicians in 2023 than any other state, this is a significant underestimate.

#### **Cost Impact on Representative Private Person or Business**

These costs will apply to licensees subject to discipline by the Board as a substance abusing licensee, or who self-refer into the PHWP.

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 thus pay \$5,439 (flat-fee) per year in years two through five, which results in total biological fluid testing costs ranging from \$277,920 to \$1.15 million per year and up to \$9.3 million over a ten-year period.

**Comment:** this frequency of testing will benefit the lab and third-party vendors, because of increased revenue, however, there is no basis for this increased rate of testing frequency. 52-104 tests in the first year is excessive, and will decrease likelihood of self-referrals. 24-36 tests in years 2-5 seems reasonable. Having an informed vendor, such as a state-voting member PHP of the Federation of State Physician Health Programs, utilizing treatment recommendations from a treating entity with expertise in treating safety-sensitive workers, such as physicians is the best way to guide decisions regarding testing frequency.

**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.

**Comment:** \$5,460 per year for a monthly support group meeting is excessive. This amounts to \$455/month. Typical costs for facilitated groups range from \$25-75/session.

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 tenyear period.

**Comment:** This requirement will make it very difficult to practice medicine. Hopefully the Board will elect to waive this requirement, when indicated.

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**#1 Uniform Standard** Refers to Board ordered evaluations (p.4/44)

**#2 Uniform Standard** "...specific criteria that the licensee must meet before being permitted to return to practice on a full-time or part-time basis." (p.6/44)

While awaiting the results of the clinical diagnostic evaluation required in Uniform Standard #1, the licensee shall be randomly drug tested at least two (2) times per week.

After reviewing the results of the clinical diagnostic evaluation, and the criteria below, a diversion or probation manager shall determine, whether or not the licensee is safe to return to either part-time or full-time practice. However, no licensee shall be returned to practice until he or she has at least 30 days of negative drug tests.

## **#4 Uniform Standard Frequency of testing** (p.8/44)

The following standards shall govern all aspects of testing required to determine abstention from alcohol and drugs for any person whose license is placed on probation or in a diversion program due to substance use:

Level I Year 1 Minimum Range of Number of Random Tests 52-104

Level II\* Year 2+ Minimum Range of Number of Random Tests 36-104

\*The minimum range of 36-104 tests identified in level II, is for the second year of probation or diversion, and each year thereafter, up to five (5) years. Thereafter, administration of one (1) time per month if there have

been no positive drug tests in the previous five (5) consecutive years of probation or diversion.

**Comment:** this frequency of testing will benefit the lab and third-party vendors, because of increased revenue, however, there is no basis for this increased rate of testing frequency. 52-104 tests in the first year seems excessive, and will decrease likelihood of self-referrals. 24-36 tests in years 2-5 seems reasonable. Having an informed PHWP, with expertise commensurate with other state-voting members of the Federation of State Physician Health Programs, utilizing treatment recommendations from a treating entity with expertise in treating physicians (safety-sensitive workers) is the best way to guide decisions regarding testing frequency.

#### **#5 Uniform Standard group support meetings** (p. 12/44)

**#7 Uniform Standard Worksite Monitoring** (p.14/44). Worksite monitoring requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors.

A board may require the use of worksite monitors. If a board determines that a worksite monitor is necessary for a particular licensee, the worksite monitor shall meet the following requirements to be considered for approval by the board.

#### **Comment:** Seems reasonable.

## **#10** Uniform Standard Specific consequences for major and minor violations. (p.18/44)

**Minor Violations** include, but are not limited to:

- 1. Untimely receipt of required documentation;
- 2. Unexcused non-attendance at group meetings;
- 3. Failure to contact a monitor when required;
- 4. Any other violations that do not present an immediate threat to the violator or to the public.

Consequences for minor violations include, but are not limited to:

- 1. Removal from practice;
- 2. Practice limitations;
- 3. Required supervision;
- 4. Increased documentation;
- 5. Issuance of citation and fine or a warning notice;
- 6. Required re-evaluation/testing;
- 7. Other action as determined by the board.

**Comment:** The reporting requirement for minor violations ensures that virtually 100% of self-referred participants will lose their confidential status with the Board, which will disincentive self-referrals, and increase the likelihood that a licensee with a substance use disorder will not seek help. All of the other reporting requirements seem reasonable to me.

**#12 Uniform Standard "Petition for Reinstatement"** as used in this standard is an informal request (petition) as opposed to a "Petition for Reinstatement" under the Administrative Procedure Act. (p.21/44).

The licensee must meet the following criteria to request (petition) for a full and unrestricted license.

- 1. Demonstrated sustained compliance with the terms of the disciplinary order, if applicable.
- 2. Demonstrated successful completion of recovery program, if required.
- 3. Demonstrated a consistent and sustained participation in activities that promote and support their recovery including, but not limited to, ongoing support meetings, therapy, counseling, relapse prevention plan, and community activities.
- 4. Demonstrated that he or she is able to practice safely.
- 5. Continuous sobriety for three (3) to five (5) years.

#### **Comment:** Continuous sobriety for 3-5 years.

#### #13 Uniform Standard (p.22/44).

1. A vendor must report to the board any major violation, as defined in Uniform Standard #10, within one (1) business day. A vendor must report to the board any minor violation, as defined in Uniform Standard #10, within five (5) business days.

## #14 Uniform Standard – disclosure (p.26/44).

If a board uses a private-sector vendor that provides diversion services, the extent to which licensee participation in that program shall be kept confidential from the public.

The board shall disclose the following information to the public for licensees who are participating in a board monitoring/diversion program regardless of whether the licensee is a self-referral or a board referral. However, the

disclosure shall not contain information that the restrictions are a result of the licensee's participation in a diversion program.

- Licensee's name;
- Whether the licensee's practice is restricted, or the license is on inactive status;
- A detailed description of any restriction imposed.

**Comment:** This Uniform Standard effectively eliminates the possibility of offering legitimate confidentiality for self-referred participants. Additionally, every licensee with a moderate or severe substance use disorder (SUD) diagnosis will likely require residential SUD treatment, requiring cessation of practice. The mandated reporting to Med Board and public posting will further stigmatize addiction and disincentivize self-referrals to PHWP. ANY DECREASE in referrals will contribute to higher likelihood of a licensee practicing with an untreated potentially impairing illness. **Summary of Comments:** 

The proposed regulatory changes in regard to implementation of SB1177.

The provisions of SB1177 clearly describe a Physician Health Program with provisions for confidentiality, providing services that are in line with requirements for State Voting membership in the Federation of State Physician Health Programs. However, the proposed language in the regulations referenced below, as well as the language in the Uniform Standards contradict the language in SB1177, and support a Medical Board operated monitoring program that does not enable confidentiality, or incentivize early intervention and treatment for self-referred participants. CCR section 1357.11 regarding mandated reporting of practice restrictions. Every licensee with a moderate or severe substance use disorder (SUD) diagnosis will likely require residential SUD treatment, requiring cessation of practice. The mandated reporting to Med Board and public posting will further stigmatize addiction and disincentivize self-referrals to PHWP. ANY DECREASE in referrals will contribute to higher likelihood of a licensee practicing with an untreated potentially impairing illness.

CCR Section 1357.12. (b) regarding consequences and reporting requirements for minor violations are concerning. Corresponds to #10 Uniform Standards Specific consequences for major and minor violations. Minor violations will likely occur in the vast majority of participants. The reporting requirement for minor violations ensures that virtually 100% of self-referred participants will lose their confidential status with the Board, which will disincentive self-referrals, and increase the likelihood that a licensee with a substance use disorder will not seek help. All of the other reporting requirements seem reasonable to me.

CCR Section 1361.5. Uniform Standards for Substance-Abusing Licensees, Biological Fluid Testing, This corresponds to #4 Uniform Standard Frequency of Testing. This frequency of testing will benefit the lab and third-party vendors, because of increased revenue, however, there is no basis for this increased rate of testing frequency. 52-104 tests in the first year seem excessive, and will decrease likelihood of self-referrals. 24-36 tests in years 2-5 seems reasonable. Having an informed PHWP, with expertise commensurate with other state-voting members of the Federation of State Physician Health Programs, utilizing treatment recommendations from a treating entity with expertise in treating physicians (safety-sensitive workers) is the best way to guide decisions regarding testing frequency. Cost Impact estimates 40 licensees will be placed in the PHWP per year for the duration of their five-year probation period. In Mississippi, and other states, PHPs will monitor 1-2% of actively practicing physicians in the state. Considering California has more active physicians in 2023 than any other state, this is a significant underestimate. The estimated cost impact of monthly support group meetings of \$5,460 per year for a monthly support group meeting is excessive. This amounts to \$455/month. Typical costs for facilitated groups range from \$25-75/session. #14 Uniform Standard – Disclosure. "The board shall disclose the following information to the public for licensees who are participating in a board monitoring/diversion program regardless of whether the licensee is a self-referral or a board referral. However, the disclosure shall not contain information that the restrictions are a result of the licensee's participation in a diversion program. Licensee's name; Whether the licensee's practice is restricted, or the license is on inactive status; A detailed description of any restriction imposed." This Uniform Standard effectively eliminates the possibility of offering legitimate confidentiality for self-referred participants. Additionally, every licensee with a moderate or severe substance use disorder (SUD) diagnosis will likely require residential SUD treatment, requiring cessation of practice, and mandated reporting to Med Board and public posting, which will further stigmatize addiction and disincentivize self-referrals to PHWP.

### 4/16/19

The Federation of State Physician Health Program Guidelines have been designed by FSPHP members with subject matter expertise to assist State Physician Health Programs (PHPs) in achieving accountability, consistency, and excellence. An earlier version of these Guidelines was developed and accepted by the Federation of State Physician Health Programs (FSPHP) in 2005. The new 2019 FSPHP PHPs Guidelines expand upon the original Guidelines, reflecting developments in the science, practice, and scope of PHP services over the past decade. Many PHPs assist healthcare professionals in addition to physicians, such as dentists, nurses, veterinarians, and/or pharmacists. The use of the Guidelines for other professionals is left to the discretion of the individual PHP.

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Linda Bresnahan, MS Executive Director

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# MEDICAL BOARD OF CALIFORNIA

# PHYSICIAN AND SURGEON HEALTH AND WELLNESS PROGRAM

Summary of Public Comments Received During the 45-Day Comment Period and Proposed Responses Regarding the Proposed Regulatory text to amend 16 CCR sections 1357, 1357.1, 1357.9, 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

• Written Comments from Abril Dozal on behalf of the Committee of Interns and Residents (CIR/SEIU) dated November 7, 2023

**Comment 1:** CIR/SEIU requests the Board significantly reduce the fee structure reflective of resident physician pay compared to attending pay because a physician in training would not be able to afford treatment through the Physician and Surgeon Health and Wellness Program (PHWP).

**Proposed Response to Comment 1:** The Board has reviewed this comment and does not recommend any changes to the language. Pursuant to Business and Professions Code (BPC) sections 2340.6(a)(6) and 2340.8(c), the individual licensees are obligated to pay the costs of their participation in the program.

Written Comments from Michele Monserratt-Ramos, Patient
 Safety Advocate, on behalf of Consumer Watchdog (CW) dated
 November 13, 2023, and Oral Testimony on November 14, 2023

**Comment 2:** CW states that the Board must ensure that the Uniform Standards are followed in dealing with substance abusing licensees and the proposed language does not explicitly state where the participants, program, and/or Board shall follow the Uniform Standards.

Proposed Response to Comment 2: The Board has reviewed this comment and does not recommend any changes to the language. Under the proposed text at Title 16 of the California Code of Regulations (CCR) section 1357(j), "Program" is defined as "the Physician and Surgeon Health and Wellness Program authorized pursuant to Article 14 commencing with Section 2340 of the code." Article 14 sets forth all the statutory requirements for the PHWP, including that it must comply with the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees (Uniform Standards) consistent with BPC section 2340.2(e). The Uniform Standards are not laws, however, without being adopted as regulations. Accordingly, the proposed text follows the requirements of the Uniform Standards, which were adopted by the Board as regulations in 2015, or are otherwise compliant with the Uniform Standards, as explained in the Initial Statement of Reasons (ISOR). Therefore, reference to the Uniform Standards in each

section of the proposed text throughout Article 2 would be duplicative, unnecessary, and confusing.

**Comment 3:** CW requests the Board include "dangerous drugs" in section 1357.1(b).

**Proposed Response to Comment 3:** The Board has reviewed this comment and does not recommend making any changes to the language. Section 1357.1(b) was amended to replace the term "dangerous drugs" with "substances" to correctly reflect the terminology used in Article 14 of the code, commencing with BPC section 2340.

**Comment 4:** CW states that section 1357.1(c) should be amended to clarify that for any participant entering the PHWP, whether voluntarily, by Board disciplinary order, or by court order that the Uniform Standards are initiated.

**Proposed Response to Comment 4:** The Board has reviewed this comment and does not recommend any changes to the language. The proposed text establishing the PHWP complies with BPC section 2340, et seq., including by complying with the Uniform Standards as explained in Proposed Response to Comment 2.

**Comment 5:** CW indicated that section 1357.1(d) needs to specify that whenever the Board orders a clinical diagnostic evaluation, the Board shall order the participant to cease practice pending the results of the evaluation and the review by the Board.

**Proposed Response to Comment 5**: The Board has reviewed this comment and does not recommend any changes to the language. The purpose of section 1357.1 is to provide the criteria for admission into the PHWP. The requirements for clinical diagnostic evaluations are addressed in section 1357.10(c). Section 1357.10(c) indicates that if the vendor or the Board requires a participant to undergo a clinical diagnostic evaluation, the participant and evaluator must comply with/meet all of the requirements set forth in 16 CCR section 1361.5(c)(1)(A)-(D), which implemented the Uniform Standards relating to clinical diagnostic evaluations, and was approved by the Office of Administrative Law (OAL) in 2015.

Comment 6: CW requests the Board add "and that failure to do so will require the participant to restart biological fluid testing on any day, at any time, including weekends and holidays per the first-year standard of 52-104 random tests per year" to section 1357.1(f), which requires the participant to agree in writing to abstain from the use of alcohol and prohibited substances.

**Proposed Response to Comment 6:** The Board has reviewed this comment and does not recommend any changes to the language. The requirements for biological fluid testing, including testing frequency, are set forth under existing section 1361.5(c)(3), and the PHWP must comply with those requirements pursuant to proposed section 1357.10(e).

**Comment 7:** CW states that section 1357.1(g) must be amended to include language that a cease practice order must be issued upon entrance into the PHWP.

**Proposed Response to Comment 7**: The Board has reviewed this comment and does not recommend any changes to the language. The purpose of section 1357 is to provide the criteria for admission into the PHWP and to make clear to participants that they may be subject to practice restrictions by the PHWP, and they must agree to comply to be admitted into the program. This comment may be in reference to clinical diagnostic evaluations, which are addressed in proposed section 1357.10(c). If a clinical diagnostic evaluation is ordered, then the licensee shall be required to cease practice pending the results of the clinical diagnostic evaluation, as required by existing section 1361.5(c)(1)(B).

**Comment 8:** CW requests that section 1357.1(h) be amended to include all elements of the agreement including abiding by the Uniform Standards for admission into the PHWP.

**Proposed Response to Comment 8:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in the Proposed Response to Comment 2.

**Comment 9:** CW indicates that section 1357.4 should not be deleted and provided the following proposed language in **bold**:

# 1357.4 Causes Denial of Admission.

- (b) The applicant has been disciplined by another state medial licensing authority specifically that the applicant has surrendered or had had a license revoked by another state medial licensing authority.
- (c) The applicant has violated section 822 and 2239 of the Business and Professions Code.
- (d) The committee recommends that the applicant will not substantially benefit from participation in the program or that the applicant's participation in the program creates too great a risk to the public health, safety, or welfare.

**Proposed Response to Comment 9:** The Board has reviewed this comment and does not recommend making any changes to the language. This section would be repealed under this rulemaking because it relates to the prior diversion program that no longer exists. Since the PHWP does not shield participants from enforcement actions, the Board is not required to dictate when the PHWP must deny admission into the program for a licensee who otherwise meets the criteria to participate and agrees to comply with the PHWP's requirements. Individuals who have had discipline in another state or have committed violations of the Medical Practice Act may benefit from participating in the PHWP for treatment and monitoring, which will also serve to protect the public.

**Comment 10:** CW indicates that section 1357.5 should not be deleted, and the language should read as indicated in **bold**:

# 1357.5 Causes for Termination from the Program.

The program manager may terminate a physician's participation in the program for any of the following reasons:

- (a)The applicant has failed to comply with the agreement (and the Uniform Standards), including but not limited to, failure to comply with the prescribed monitoring or treatment regimen, use of alcohol or other unauthorized drug; or refusal to stop practice when directed to do so by the committee.
- (b) Any cause for denial of an applicant in Section 1357.4 which includes: The program manager may deny an applicant admission to the program for any of the following reasons:
  - (a) The applicant does not meet the requirements set forth in Section 1357.1.
  - (b) The applicant has been disciplined by another state medical licensing authority.
  - (c) Complaints or information have been received by the division which indicate that the applicant may have violated a provision of the Medical Practice Act or committed any other act that would be grounds for discipline, excluding Sections 822 and 2239 of the code.
  - (d) The committee recommends that the applicant will not substantially benefit from participation in the program or that the applicant's participation in the program creates too great a risk to the public health, safety, or welfare.

    Cal. Code Regs. Tit. 16, § 1357.4.
- (d) The committee recommends that the applicant will not benefit from further participation in or has not substantially benefitted from participation in the program or that the applicant's continued participation in the program creates too great a risk to the public health, safety, or welfare.

**Proposed Response to Comment 10:** The Board has reviewed this comment and does not recommend making any changes to the language. This section would be repealed under this rulemaking because it relates to the prior diversion program that no longer exists. Since the PHWP does not shield participants from enforcement actions, the Board is not required to dictate when the PHWP must terminate a participant's contract. Under proposed section 1357.12, the PHWP is obligated, however, to report each individual to the Board within the specified time period who has committed a major or minor violation, or withdraws or is terminated from the program, which will trigger the opening of a complaint by the Board for review and disciplinary action as warranted.

**Comment 11:** CW indicates that section 1357.6 should not be deleted and provided the following proposed language in **bold**:

# 1357.6 Notification of Termination.

Whenever any applicant who is self-referred is terminated from the program and has been determined to present a threat to the public health or safety, the program manager shall report such fact to the division and the board, without the inclusion of any confidential information. When reporting a termination to the board, the Uniform Standards are implemented.

**Proposed Response to Comment 11:** The Board has reviewed this comment and does not recommend making any changes for the reasons set forth in Proposed Response to Comment 10.

**Comment 12**: CW requests the following types of records in **bold** be added to section 1357.9 and be required to be maintained by the program for seven years from the date of creation by the program:

- c) All correspondence with the Enforcement Program.
- d) All committee letters.
- f) Computerized records derived from any of the foregoing types of documents.

**Proposed Response to Comment 12**: The Board has reviewed this comment and does not recommend any changes to the language. Correspondence with the Enforcement Program is covered under the requirement to preserve correspondence with the Board. The PHWP text does not include a committee, but if that changes, a committee of the Board is part of the Board, so communications between the committee and the PHWP would be covered. Computerized records are already required to be preserved under the proposed text.

**Comment 13:** CW proposed that the requirement to follow all sections of the Uniform Standards be added to the proposed text under section 1357.10(a).

**Proposed Response to Comment 13:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in the Proposed Response to Comment 2.

**Comment 14:** CW proposed that 1357.10(b) be modified as indicated in **bold**:

(b) Participants shall meet the criteria set forth in section 1357.1 including agreeing to a cease practice order and agrees to cooperate and comply with all the Uniform Standards.

**Proposed Response to Comment 14:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in the Proposed Response to Comment 2. Additionally, the participants are required to agree in writing to comply with all practice restrictions under the proposed text for 1357.1(g).

**Comment 15:** CW indicated that the vendor or Board should require all participants to undergo a clinical diagnostic evaluation as a requirement to participate in the program, and states that both self-referred and Board-referred participants must comply with the Uniform Standards.

**Proposed Response to Comment 15:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in the Proposed Response to Comment 2. Additionally, the requirements for a clinical diagnostic evaluation are addressed under proposed section 1357.10(c). If a clinical diagnostic evaluation is ordered, then it must follow the provisions of that section.

**Comment 16:** Under proposed section 1357.10(e) addressing biological fluid testing, CW states, "All the regulations related to biological testing must require participants to comply with the Uniform Standards whether the participant is a self-referral or referred to by the board."

Additionally, under section 1357.10(e)(2)(A), CW proposes to add language at the end of the last sentence to say, "and the participant will adhere to a cease practice order and comply to all elements of the Uniform Standards."

**Proposed Response to Comment 16:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in the Proposed Response to Comment 15.

**Comment 17:** Under proposed section 1357.10(f) addressing positive biological fluid tests, CW proposes adding language to state, <u>"and the vendor and the participant will adhere to the Uniform Standards."</u>

**Proposed Response to Comment 17:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in the Proposed Response to Comment 2.

**Comment 18:** Under proposed section 1357.10(g) addressing requirements for testing locations/laboratories and specimen collectors, CW proposes adding language the following language in **bold**:

"Whether the participant is board-referred or a self-referral, the vendor and the participant must comply with the Uniform Standards."

**Proposed Response to Comment 18:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in the Proposed Response to Comment 2.

**Comment 19:** Under proposed section 1357.10(h) relating to the type of treatment that a participant shall be required to undergo, CW proposes to add the language or made the comments in **bold** under subdivisions 1, 3, 4, and 9, as follows:

- (1) If the participant is required to undergo a clinical diagnostic evaluation as specified in section 1357.10, the recommendation of the clinical diagnostic evaluation. All participants whether self-referred or board referred must undergo a clinical diagnostic evaluation and comply with the Uniform Standards:
- (3) Participant's history (If a participant has lapsed while in the program with a failed biological fluid test, a missed biological fluid test, or a fraudulent biological fluid test, the participant must adhere to the Uniform Standards);
- (4) <u>Documented length of sobriety/time that has elapsed since substance abuse</u> (If a participant's sobriety has lapsed while in the program, the participant must comply with the Uniform Standards and adhere to a cease practice order and start over with the first-year testing schedule);
- (9) Whether the participant is a threat to themselves or the public. If the participant is a threat to themselves or the public, the vendor must report the participant to the board and the board must issue a cease practice order and suspend the license until the participant is fit to practice medicine.

Additionally, CW copied language from 1357.1(h) relating to the criteria for admission into the program and included it in this comment as subdivision (i) between section 1357.10(h) and (h)(1).

Proposed Response to Comment 19: The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in the Proposed Response to Comment 15. Additionally, the purpose of section 1357.10(h) is to set forth the factors that the vendor and its contractors must consider when determining the type of treatment a participant shall be required to undergo. CW's additional proposed language and comments are already addressed to the extent warranted in other proposed sections such as those relating to biological fluid testing under proposed section 1357.10(e), and reporting requirements for participant violations, withdrawals, and terminations under proposed section 1357.12. Finally, the requirement for the participant to agree in writing to cooperate with all elements of the agreement for admission into the program and to pay all costs is already addressed under proposed section 1357.1(h) and does not need to be restated under proposed section 1357.10.

**Comment 20:** Under proposed section 1357.10(i)(5), which CW misidentified as subdivision (j), CW proposes to add language to require the treatment plans to comply with the Uniform Standards.

**Proposed Response to Comment 20:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in the Proposed Response to Comment 2.

**Comment 21:** Under proposed section 1357.10(I), CW proposes to add language to indicate that both self-referred and Board referred participants must comply with all the Uniform Standards and that this must be considered when the decision is made on whether the participant should return to practice.

**Proposed Response to Comment 21:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in the Proposed Response to Comment 2.

**Comment 22:** Under proposed section 1357.11, relating to reporting and disclosing practice restrictions for participants, CW made the following comments/suggested language in **bold**:

If a vendor imposes a practice restriction on a participant, the vendor shall report it in writing to the Board within one (1) business day, and the Board shall make the following information public on the participant's profile on the Board's website: 1). The participant's name 2) whether the participant's license is restricted or in a non-practice status (it must be listed under secondary status on the physician profile) 3) a detailed description of each restriction imposed. If the participant self-referred and the enrollment in the program was not a condition of probation, then the public shall not contain information that the restriction or non-practice status is the result of the participant's enrollment in the program (the cease practice order or practice restriction must still be listed under the secondary status on the physician profile). The Board shall remove the practice restriction from the participant's profile but not from the board enforcement documentation itself because a practice restriction whether the applicant is self-referred or board referred would call for the board to start the enforcement process, investigate the physician.

**Proposed Response to Comment 22:** The Board has reviewed this comment and does not recommend any changes to the language. CW's comments do not appear to relate to the PHWP, but rather how a practice restriction is reported on the licensee's profile by the Board. Further, a practice restriction alone will not trigger the Board to open a complaint and start the enforcement process. For example, a self-referred physician may have a practice restriction imposed while they are being evaluated, but this would not result in the Board opening a complaint. In contrast, a practice restriction that is imposed because the licensing committed a major or minor violation will trigger the enforcement process.

**Comment 23:** Under proposed section 1357.12, regarding reports of participant violations, withdrawals, and terminations to the Board as well as inquiries by the Board, CW made the following comments/proposed text in **bold**:

- (a) The vendor shall report in writing to the Board each major violation by a participant, as defined in Section 1361.52 (a), within one (1) business day of the vendor's finding that the participant committed a major violation, and shall identify the name and license number of the participant, and a detailed description of the violation(s), including the type and date of each occurrence and the applicant and the board must follow the Uniform Standards meaning the participant will be ordered to cease practice, the applicant must undergo a new clinical diagnostic evaluation, the applicant must test negative for at least a month of continuous drug testing before being allowed to go back to work, or termination of agreement, and referral for discipline.
- (b) The vendor shall report in writing to the Board each minor violation by a participant, as defined in section 1361.52 (c) within five (5) business days of the vendor's finding that the participant committed a minor violation, and shall identify the name and license number of the participant, and a detailed description of the violation(s), including the type and date of each occurrence and the applicant and the board must follow the Uniform Standards meaning the Board can remove the participant from practice, place practice limitations on the participant, require supervision, increase documentation, issue a citation or fine, require re-evaluation/testing, or other action determined by the Board.
- (c) The vendor shall report in writing to the Board any participant who withdraws or is terminated from the program within one (1) business day of the withdrawal or termination, and shall identify the name and license number of the participant, the date the participant enrolled in the program, the date of the withdrawal or termination from the program, and a description of the circumstances leading up to the withdrawal or termination. The board shall follow the uniform standards and investigate the reason for the termination, issue a cease practice order, and take potential further action on the participant's license.
- (d) If the Board inquires as to whether a licensee is a participant in the program after initiating an investigation on the licensee, the vendor shall provide a written response within three (3) business days of the inquiry indicating whether the licensee is a participant in the program and the Board shall comply with the Uniform Standards commencing with a cease practice order.

**Proposed Response to Comment 23:** The Board has reviewed this comment and does not recommend any changes to the language. Proposed section 1357.12 sets forth the reports that the vendor must make to the Board regarding major and minor

violations, withdrawals and terminations and requires the vendor to respond to inquiries by the Board on whether a licensee is a participant in the program after initiating an investigation on the licensee. CW's comments are directed to what happens after the Board receives the information provided under this section and are not on point with this proposed section.

**Comment 24:** Under proposed section 1357.13, regarding vendor communications with the Board and annual reports, CW requested a new subdivision (15) in **bold** be added to require the vendor to report the following to the Board:

(15) The number of times the Uniform Standards were used and which regulations from the Uniform Standards that the vendor utilized. The number of Uniform Standards that the applicants did not comply with, and which Uniform Standards did they not adhere to.

**Proposed Response to Comment 24:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in Proposed Response to Comment 2.

**Comment 25:** CW states that section 1361.5(c)3(l)(6) should be amended because the reduction in testing frequency was not meant for physicians, but rather other healthcare licensees with salaries not equivalent to physicians, such as respiratory therapists. CW is concerned that any physician on probation could fall into the minimum of 50% supervision per day. CW stated that the biological fluid testing schedules for the first and second years should not change for physicians and that the Uniform Standards must be followed.

**Proposed Response to Comment 25:** The Board has reviewed this comment and does not recommend any changes to the language, because this change is required to be consistent with the modifications made to Uniform Standard #4, effective March 2019. The changes to Uniform Standard #4 did not include any limitations as to which licensees they applied to; therefore, this is an option that must be included in the Board's regulations implementing the Uniform Standards.

 Written Comments from Marcus Friedman, Administrative Director, Consumer Protection Policy Center (CPPC) dated November 13, 2023

**Comment 26:** CPPC states that it is the Board's burden to ensure that the language of the proposed regulations is consistent with the Uniform Standards. CPPC referenced BPC section 315 and 2340.2(e) indicating that neither statute draws a distinction between self-referred and Board-referred participants. CPPC states that the Board's proposed regulations imply that there are different treatment requirements for self-referrals versus Board-referrals, and that self-referred participants are not fully subject to the Uniform Standards. CPPC requests the Board modify the proposed language to make clear that there is no difference in how self-referred and Board-referred participants are to be treated by the PHWP.

Proposed Response to Comment 26: The Board has reviewed this comment and does not recommend any changes to the language. Pursuant to the proposed text under section 1357(j), "Program" is defined as "the Physician and Surgeon Health and Wellness Program authorized pursuant to Article 14 commencing with Section 2340 of the code." Article 14 sets forth all the statutory requirements for the PHWP, including that it must be compliant with the Uniform Standards consistent with BPC section 2340.2(e). The Uniform Standards are not laws, however, without being adopted as regulations. Accordingly, the proposed text follows the requirements of the Uniform Standards, which were adopted by the Board as regulations in 2015, as explained in the Initial Statement of Reasons (ISOR).

In addition, the proposed text under section 1357(h), defines "Participant" as "a licensee enrolled in the program pursuant to a signed agreement with the program, regardless of whether the licensee enrolled pursuant to a condition of probation imposed by the Board, or as a self-referral." Thus, the requirements imposed on "participants" apply without distinction to both Board-referred and self-referred participants.

Pursuant to BPC section 2340.1(d), however, the program must provide for the confidential participation of a licensee with substance abuse issues who does not have a restriction on their practice relating to those substance abuse issues. Consequently, the proposed text does distinguish between communicating with the Board for Board-referred participants versus communicating with the Board for self-referred participants, as required by statute. If, however, the self-referred participant commits a major or minor violation or withdraws or is terminated from the program, or if a practice restriction is imposed, this is reported to the Board, just like it is for Board-referred participants pursuant to proposed sections 1357.11 and 1357.12.

Comment 27: With regard to clinical diagnostic evaluations (CDE), CPPC states that Uniform Standard #1 requires all participants to undergo a CDE and that Uniform Standard #2 requires 1) all participants to cease practicing medicine pending the results of the CDE, 2) all participants to undergo twice-weekly drug testing during the cease practice period, and 3) prohibits any return to practice until the participant has demonstrated 30 days of negative drug tests. CPPC further points out that Uniform Standards #1 and #2 make no distinction between self-referred participants and Board-referred participants.

In addition, CPPC points out that existing regulation section 1361.5(c), specifies the requirements of Uniform Standard #1 being applicable to a Board-referred participant, and contends that proposed section 1357.10(c) is arguably duplicative of section 1361.5(c) in violation of Government Code sections 11349(f) and 11349.1(a).

CPPC further states that proposed section 1357.10(c) implies that a CDE is optional for a self-referred participant but argues that no option exists in Uniform Standard #1, raising consistency and clarity issues. CPPC also states that proposed section 1357.10(h)(1) also implies that the CDE is optional. CPPC requests that the Board clarify to the vendor that Uniform Standard #1 and #2 must apply to all participants.

**Proposed Response to Comment 27:** The Board has reviewed this comment and does not recommend any changes to the language. First, Uniform Standard #1 does not require any licensee to undergo a CDE. If, however, the licensee is ordered to undergo a CDE regardless of whether they are a Board-referred or self-referred participant, the CDE must meet the specified requirements. Additionally, ordering a CDE triggers the application of the practice restriction and testing requirements referred to in Uniform Standard #2.

Second, the Board adopted the Uniform Standards through regulation in 2015. Consequently, under proposed section 1357.10(c) relating to CDEs, this proposed rulemaking refers to the applicable regulatory section for the CDE requirements in existing section 1361.5(c)(1)(A)-(D). In referring to the already-adopted regulation, the Board avoided duplicating the existing regulation under a different section.

Finally, since BPC section 2340.2(d) requires the PHWP to provide for the confidential participation by a licensee who does not have a practice restriction based on substance abuse issues, it is necessary for the Board to include proposed section 1357.10(c) to require communication with the Board and the vendor for Board-referred participants and communication only with the vendor for self-referred participants regarding the results of the CDE. Nothing in proposed section 1357.10(c) exempts a self-referred participant from undergoing a CDE if required by the program.

**Comment 28:** CPPC states that Uniform Standard #3 concerning the ability of a healing arts board to communicate with a participant's employer or supervisor, has no distinction between self-referred participants and Board-referred participants. In addition, CPPC states that proposed section 1357.10(d) is duplicative of existing Board regulation 1361.5(c)(2). Furthermore, CPPC indicates that nothing in proposed section 1357.10(d) indicates that a vendor must require a self-referred participant to permit communication between the PWHP and the participant's employer or supervisor. Lastly, CPPC states that there is an inconsistency between this proposed section and proposed section 1357(e), which creates an inconsistency and a lack of clarity between the two sections that may permit a vendor to treat self-referred participants differently from Board-referred participants.

**Proposed Response to Comment 28:** The Board has reviewed this comment and does not recommend any changes to the language. The proposed text under section 1357.10(d) requires all participants regardless of whether they are Board-referred or self-referred to comply with all the notification and consent requirements set forth in existing regulation section 1361.5(c)(2).

Because BPC section 2340.2(d) requires the PHWP to provide for the confidential participation by a licensee who does not have a practice restriction based on substance abuse issues, it is necessary for the Board to include proposed section 1357.10(d) to require that the communication and authorizations apply to the Board and the vendor for Board-referred participants and only to the vendor for self-referred participants.

Finally proposed section 1357(e) simply provides a definition for "employer," which applies to all participants, and is not inconsistent with proposed section 1357.10(d), which provides that if the participant has an employer or supervisor, the participant shall comply with all the notification and consent requirements set forth in existing section 1361.5(c)(2).

**Comment 29:** CPPC states that proposed sections 1357.10(e)(2), 1357.10(g), 1357.10(j), 1357.10(k), and 1357.10(l) are confusing and unclear as it relates to self-referred participants being treated differently from Board-referred participants, which is not allowed in the Uniform Standards.

**Proposed Response to Comment 29:** The Board has reviewed this comment and does not recommend any changes to the language. The Board agrees that the law requires the PHWP to comply with the Uniform Standards, and the Board does so by writing the proposed sections at issue so that they refer to the existing regulations that adopted the Uniform Standards into law in 2015 or are otherwise compliant with the Uniform Standards.

BPC section 2340.2(d), however, requires the PHWP to provide for the confidential participation by a licensee who does not have a practice restriction based on substance abuse issues. Consequently, while Board-referred and self-referred participants must comply with the program requirements, which are consistent with the Uniform Standards, this rulemaking must indicate under proposed sections 1357.10(e)(2), 1357.10(g), 1357.10(j), 1357.10(k), and 1357.10(l) that references to the "Board" in existing regulations mean the Board and the vendor for Board-referred participants and mean only the vendor for self-referred participants. This rulemaking must also make clear that references to "probation" in applicable sections, mean probation ordered by the Board for Board-referred participants, and mean the terms of the participant's monitoring agreement with the vendor for self-referred participants. This distinction is necessary to provide for the confidential participation of a self-referred participant, but it does not change the requirement that the program and participants must comply with the Uniform Standards as adopted via regulation.

**Comment 30**: CPPC states that proposed section 1357.11 must be rejected for lack of authority under Government code sections 11349 and 11349.1 because there is no statute that authorizes the vendor to impose restrictions on a participant's medical practice and that can only be done by the Board.

**Proposed Response to Comment 30:** The Board has reviewed this comment and does not recommend any changes to the language. Pursuant to BPC section 2340.4(a), if the Board establishes a program, the Board shall contract for the program's administration with a private third-party independent administering entity pursuant to a request for proposals.

BPC section 2340.2(d) requires the PHWP to provide for the confidential participation by a licensee who does not have a practice restriction based on substance abuse issues.

Proposed section 1357.1(g), which sets forth the criteria for admission into the program, requires each participant to agree in writing to comply with all practice restrictions imposed by the program. This is a contractual requirement, just like the other requirements for admission. If the licensee does not agree to this term, then they will not be allowed to participate in the program.

Once a practice restriction is imposed by the program, the program is required to report the practice restriction to the Board under proposed section 1357.11, and the Board is then required to post the restriction on the licensee's profile but must not reveal that the restrictions are a result of the licensee's participation in the program. The Board included proposed section 1357.11 to be compliant with Uniform Standard #14.

**Comment 31:** CPPC states that if the Board decides to implement SB 1177 by creating a new PHWP, it must also create a mechanism by which Board members actively supervise the functioning of the program and says that the proposed regulations should establish a standing board committee to oversee the PHWP.

**Proposed Response to Comment 31:** The Board has reviewed this comment and does not recommend any changes to the language. Pursuant to BPC section 2340.4(a) if the Board establishes a program, the Board shall contract for the program's administration with a private third-party independent administering entity pursuant to a request for proposals. Additionally, the program is required to submit to an audit every three years, and as otherwise required by the Board, pursuant to proposed section 1357.14 for the assessment of the vendor's performance in adhering to the contract requirements applicable to the program.

Additionally, although this program must allow for the confidential participation by a licensee who does not have a practice restriction based on substance abuse issues pursuant to BPC section 2340.2(d), participation in the program will not shield licensees from enforcement actions, and it is, therefore, structured very differently from the Board's defunct diversion program.

**Comment 32:** CPPC states in its conclusion that the Board must reject these proposed regulations as unclear, inconsistent with two statutes and the Uniform Standard, duplicative of other Board regulations and unauthorized.

**Proposed Response to Comment 32:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in the Proposed Responses to Comments 26-31.

 Written Comments from Randolph P. Holmes, M.D., on behalf of the California Society of Addiction Medicine (CSAM) dated November 14, 2023

**Comment 33**: CSAM requests the program title be changed or clarified that the program only handles substance use disorders and not mental health conditions

because the title of PHWP implies that it covers other potential health/wellness conditions

Proposed Response to Comment 33: The Board has reviewed this comment and does not recommend any changes to the language. Pursuant to BPC sections 2340(a) and (b), the authorized program is called the Physical and Surgeon Health and Wellness Program. Since this is set forth in statute, the Board is unable to change the name. Additionally, although the PHWP only offers monitoring and treatment services for substance use disorders, BPC section 2340.2(a) requires the program to provide for the education of all licensed physicians with respect to the recognition and prevention of physical, emotional, and psychological problems.

**Comment 34**: The vendors contracted by the Board must be done in a transparent way to ensure that the Uniform Standards are followed, treatment goals and expected outcomes need to be consistent across vendors, and operations, ideology, and routine practices should be open to examination.

Proposed Response to Comment 34: The Board has reviewed this comment and does not recommend any changes to the language. Pursuant to BPC section 2340.4(a), the Board is required to contract for the administration of the PHWP with a private third-party independent administering entity pursuant to a request for proposals (RFP), Article 4 (commencing with Section 10335) of Chapter 2 of Part 2 of Division 2 of the Public Contract Code. This is a transparent process and ensures that the vendor selected complies with all applicable laws and has the expertise, as well as the level of staff, to administer the PHWP. Additionally, the program is required to submit to an audit every three years, and as otherwise required by the Board, pursuant to proposed section 1357.14 for the assessment of the vendor's performance in adhering to the contract requirements applicable to the program.

**Comment 35:** CSAM requests the Board waive the cost recovery for physicians who successfully complete the PHWP, stating that this would lower the barrier to reentry to normal practice for physicians who have taken meaningful steps towards recovery.

**Proposed Response to Comment 35:** The Board has reviewed this comment and does not recommend any changes to the language. Pursuant to BPC sections 2340.6(a)(6) and 2340.8(c), the individual licensees are obligated to pay the costs of their participation in the program. Since this is a statutory requirement, the Board is unable to waive any fees.

Additionally, if this comment is referring to waiving cost recovery imposed in a disciplinary decision, cost recovery is negotiated at the time of settlement or is contained in a proposed decision adopted by the Board to recover costs that have already been spent by the Board for the investigation and prosecution of the disciplinary matter pursuant to BPC section 125.3. The Board will not waive cost recovery after the fact under these circumstances.

**Comment 36:** CSAM requests that the Board establish a mechanism for regular reviews by subject matter expert professionals in the field that can send information and recommendations to the Board about the program effectiveness.

Proposed Response to Comment 36: The Board has reviewed this comment and does not recommend any changes to the language. Pursuant to proposed section 1357.13, the vendor will be required to provide detailed de-identified information about the participants and the effectiveness of the program, at least annually for inclusion in the Board's annual report, which is public. Additionally, under proposed section 1357.14, the program will be subject to regular independent audits at least every three years, or as requested by the Board to assess the vendor's performance in adhering to the contract requirements applicable to the program. These provisions are consistent with the statutory authority for establishing the program and will ensure the PHWP is monitored regularly to evaluate its compliance with the applicable statutes and regulations and its effectiveness in assisting licensees with substance abuse issues and in protecting the public.

**Comment 37:** CSAM stated that the regular audits should not be vendor financed, but should be state-budgeted and should be RFP's for UC medical university research groups.

**Proposed Response to Comment 37:** The Board has reviewed this comment and does not recommend any changes to the language. BPC section 2340.6(a) requires the participants to pay for the cost of their participation in the program. Regular audits are a requirement of the program. Further, BPC section 2340.8(b) requires the Board to set a fee amount at a level sufficient to cover all costs for participating in the program, including administrative costs.

**Comment 38:** CSAM requests an amendment to proposed section 1357.9 to include language that a participant must be notified when a request for their records is received.

**Proposed Response to Comment 37:** The Board has reviewed this comment and does not recommend any changes to the language. Pursuant to BPC section 2340.6, the Board will have to pursue obtaining records through the regular discovery process, if the Board does not already have access to the records pursuant to an order of probation.

# • Written Comments from Dr. Stefanie Simmons dated November 14, 2023

**Comment 38:** Dr. Simmons states that the program as written appears to only provide for substance abuse monitoring and that for the best protection for physicians and patients, the program should be revised to include the following:

- 1. Confidentiality from the Board unless patient safety is at risk.
- 2. Proactive treatment for all potentially impairing conditions, not just substance use disorders.

- 3. Clear communication of the costs and limits of confidentiality in the program.
- 4. Inclusion of licensed health workers beyond physicians.

**Proposed Response to Comment 38:** The Board has reviewed this comment and does not recommend any changes to the language pursuant, in part, to the reasons set forth in Proposed Response to Comment 33.

With regard to confidentiality, the program does allow for the confidential participation of physicians who do not have a restriction on their practice related to substance abuse issues. Therefore, pursuant to BPC section 2340.2(d), a physician may self-refer into the program and the Board will not be notified, unless the participant commits a major or minor violation, withdraws or is terminated from the program, or practice restrictions are imposed by the program. Such events are required to be reported to the Board pursuant to proposed sections 1357.11 and 1357.12. Further, if practice restrictions are imposed by the program, the practice restriction will be posted on the licensee's profile without identifying that the licensee is a participant in the PHWP pursuant to proposed section 1357.11.

# • Written Comments and Oral Testimony from Marian Hollingsworth dated November 14, 2023

**Comment 39:** Ms. Hollingsworth states that it is a conflict of interest for the Board to establish the PHWP because it puts the Board on the side of doctors over the safety of consumers, and it is a conflict of interest for doctors to pay the Board a fee yet to be determined under BPC section 2340.8.

Proposed Response to Comment 39: The Board has reviewed this comment and does not recommend any changes to the language. Pursuant to BPC section 2340, the Board may establish the PHWP for the early identification of, and appropriate interventions to support a physician in their rehabilitation from, substance abuse to ensure that the physician remains able to practice medicine in a manner that will not endanger the public health and safety and that will maintain the integrity of the medical profession. Consumer protection is the Board's top priority, and the provisions of the program comply with the Uniform Standards and further consumer protection. Additionally, participation in the program will not shield a licensee from the enforcement process.

With regard to the fees to be paid, pursuant to BPC sections 2340.6(a)(6) and 2340.8(c), the individual licensees are obligated to pay the costs of their participation in the program, and BPC section 2340.8(b) requires the Board to adopt regulations to determine the fee to pay to the Board for participation in the program.

**Comment 40:** Ms. Hollingsworth commented that it is appalling that section 1357.13(a)(9) requires the program to report the number of patients harmed by a participant while the participant was enrolled in the PHWP, and asked if the Board expects patients to be harmed by participants in this program.

**Proposed Response to Comment 40:** The Board has reviewed this comment and does not recommend any changes to the language. BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standard #16 sets forth criteria to be reported by the Board relating to substance abusing licensees. Proposed section 1357.13(a)(9) asks for the number of patients harmed by a participant while the participant was enrolled in the PHWP, because this information is required by Uniform Standard #16.

**Comment 41**: Ms. Hollingsworth referred to the proposed language in section 1357.14 and asked how the Board will know which participants are non-compliant if the audit report does not identify the participants by name, and how this protects the public.

**Proposed Response to Comment 41:** The Board has reviewed this comment and does not recommend any changes to the language. Participants who commit a major or minor violation or who withdraw or are terminated from the program are required to be reported to the Board under proposed section 1357.12, which will trigger the opening of a complaint by the Board for review and disciplinary action as warranted. The audit will determine if the vendor is complying with this requirement.

BPC section 2340.4(g)(2) requires the vendor to submit to periodic audits and inspections of all operations, records and management relating to the program to ensure compliance with the applicable statutes, rules, and regulations for the PHWP. This section also requires that confidentiality be maintained and prohibits the audit report from disclosing any information identifying a program participant. The purpose of the audit is to evaluate and report on the conduct of the program so that if the vendor is not compliant, then the Board can take action to bring the vendor into compliance or terminate the contract pursuant to proposed section 1357.14(d).

**Comment 42**: Ms. Hollingsworth stated that the PHWP does not follow the Uniform Standards and requested the Board review them prior to implementing the PHWP.

**Proposed Response to Comment 42:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in Proposed Response to Comment 2.

**Comment 43:** Ms. Hollingsworth stated the PHWP should not be confidential, and participants should be required to inform their patients if they are participating in the PHWP.

**Proposed Response to Comment 43:** The Board has reviewed this comment and does not recommend any changes to the language. BPC section 2340(d) provides for the confidential participation by a physician with substance abuse issues who does not have a restriction on their practice related to those substance abuse issues. If the vendor imposes a practice restriction, however, the vendor will be required to report it in writing to the Board, and the Board will post the practice restriction on the licensee's profile to alert the public pursuant to proposed section 1357.11. Additionally, for Board-referred participants, the participants' order of probation is a public document posted on

the licensee's profile. Any additional practice restrictions imposed by the vendor will likewise be reported to the Board and posted on the licensee's profile to alert the public pursuant to proposed section 1357.11.

## Written Comments and Oral Testimony from Lucas Evensen on behalf of the California Medical Association (CMA) dated November 14, 2023

**Comment 44:** CMA recommends that the PHWP name be changed to "Physicians and Surgeon Health Program" to avoid physicians assuming it offers mental health treatment because the term wellness is associated within the medical community with improving one's mental health. If this is not possible, CMA requests the Board add a requirement that the vendor provide a disclaimer clarifying the program only addresses disorder and a redirection to appropriate resources and requests the following amendment in **bold** to proposed section 1357.10(a):

The vendor shall comply with and is responsible for ensuring that all contractors and subcontractors comply with the Board's requirements contained in Article 14 of the Code and this article. In addition, the vendor is obligated to comply with and bears responsibility for ensuring that all contractors and subcontractors adhere to the requirement of posting clear disclaimers at every participants entry point, including but not limited to the program website, call center interactions, and associated materials. The prescribed disclaimer must explicitly communicate that the program is exclusively dedicated to addressing substance use disorders among physicians and surgeons.

**Proposed Response to Comment 44:** The Board has reviewed this comment and does not recommend any changes to the language. Pursuant to BPC sections 2340(a) and (b), the program is authorized as the Physician and Surgeon Health and Wellness Program. Additionally, although the PHWP only offers monitoring and treatment services for substance use disorders, BPC section 2340.2(a) requires the program to provide for the education of all licensed physicians with respect to the recognition and prevention of physical, emotional and psychological problems.

**Comment 45:** CMA indicated that the high cost to participate in the PHWP will most likely discourage some physicians from self-referral and asks that the Board consider other options to lower the barriers for physicians referred to the PHWP as part of the disciplinary process who successfully complete the PHWP. CMA suggests that the Board waive cost recovery and that any costs that have been paid be reimbursed when a Board-referred physician successfully completes the PHWP as a condition of probation. CMA requests the following language in **bold** be added to section 1357.1(h):

The applicant participant agrees in writing to cooperate with all elements of the diversion agreement for admission into the program, including all sections of this article, and to pay all costs required for participation in the program. Cost recovery amounts assigned to board-mandated participants disciplined.

for substance abuse problems shall be expunged upon successful program completion. Payments to cost recovery assignments already made by the participants who successfully complete the program shall be reimbursed.

**Proposed Response to Comment 45:** The Board has reviewed this comment and does not recommend any changes to the language. Pursuant to BPC sections 2340.6(a)(6) and 2340.8(c), the individual licensees are obligated to pay the costs of their participation in the program.

Additionally, cost recovery is negotiated at the time of settlement or is contained in a proposed decision adopted by the Board to recover costs that have already been spent by the Board for the investigation and prosecution of the disciplinary matter pursuant to BPC section 125.3. The Board will not waive cost recovery after the fact under these circumstances.

**Comment 46**: CMA requests that the audit reports be available to participants and the public. CMA requests the following language in **bold** be added to proposed section 1357.14:

(f) The audit reports referenced in this section shall be provided to the participant upon request. Also, privacy law-compliant redacted audit reports may be made available to the public upon request.

**Proposed Response to Comment 45:** The Board has reviewed this comment and does not recommend any changes to the language. The public's access to public records is controlled by the California Public Records Act (CPRA) under Government Code section 7920.000, et seq. Records that are not authorized to be withheld under the CPRA are required to be produced.

**Comment 46**: CMA requests that participants be notified by the PHWP whenever their records have been shared with the Board. CMA requests the following language in **bold** be added under proposed section 1357.12:

## (e) A participant shall be notified by the program when a participant's records are shared with the Board.

**Proposed Response to Comment 46:** The Board has reviewed this comment and does not recommend any changes to the language. The program will not be sharing the participant's records with the Board pursuant to proposed section 1357.12, but rather providing a vendor report to the Board about the participant's major or minor violations, or withdrawal or termination, as well as any practice restrictions imposed on the participant. By being a participant in the program, the participant is on notice that such reports to the Board are required.

**Comment 47:** CMA requests that subsection 1357(c) related to conflicts of interest be deleted to avoid confusion as conflicts of interest involving participants are not referenced in the regulations. CMA also states that conflicts of interest are only

addressed in proposed section 1357.14(a), which concerns conflicts of interest between the vendor and program and requests the language be amended to section 1357.14(a) to include professional conflicts of interest as follows in **bold**:

At least once every three (3) years, and at any other time requested by the Board with at least 90 days' notice from the Board, an external, independent audit shall be conducted by a qualified reviewer or review team from outside the Department of Consumer Affairs with no conflict of interest with the vendor (i.e., no reviewer or individual on a review team has a current or prior business, professional, personal, or financial relationship with the vendor or any employee or officer of the vendor) providing the monitoring services. In addition, the reviewer shall not be a part of or under the control of the Board. The independent reviewer or review team must consist of licensed certified public accountant(s) or public accountant(s) who have at least five (5) years' experience in the professional practice of internal auditing and assessment processes and are qualified to perform audits of monitoring programs. The cost of the audits shall be borne by the vendor and factored into each participant's fee.

Proposed Response to Comment 46: The Board has reviewed this comment and does not recommend any changes to the language. The language in proposed section 1357(c) is to ensure that individuals performing services as part of the PHWP do not have a financial, personal, or familial relationship with the participant, or other relationship that could reasonably be expected to compromise the ability of the other to render impartial and unbiased reports. This definition is applicable to relationships with participants as well as other relationships "that could reasonably be expected to compromise the ability of the other to render impartial and unbiased reports." Further, the language in proposed section 1357.14(a) sets forth the qualifications for the auditor to ensure they are competent and do not have a conflict of interest. The language as written is sufficient to exclude an auditor with a professional conflict of interest with the vendor.

 Written Comments from Paul Yoder, Legislative Advocate on behalf of the California State Association of Psychiatrists (CSAP) dated November 14, 2023

**Comment 47:** CSAP indicates that it opposes the new diversion program because it will interfere with appropriate treatment and unfairly stigmatize and destroy the careers of physicians who are in recovery as well as interfere with diagnosis and treatment by specialists in addiction. CSAP opposes the proposed regulations unless amended. CSAP has concerns with the title of the program and requests it be changed to clarify that it only handles substance use disorder and does not treat or address mental health conditions. Therefore, CSAP requests the following amendment in **bold** to proposed section 1357.10(a):

The vendor shall comply with and is responsible for ensuring that all contractors and subcontractors comply with the Board's requirements contained in Article 14 of the Code and this article. In addition, the vendor is obligated to comply

with and bears responsibility for ensuring that all contractors and subcontractors adhere to the requirement of posting clear disclaimers at every participant entry point, including but not limited to the program website, call center interactions, and associated materials. The prescribed disclaimer must explicitly communicate that the program is exclusively dedicated to addressing substance use disorders among physicians and surgeons.

**Proposed Response to Comment 47:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in Proposed Response to Comment 44. Further, the PHWP is not a diversion program designed to shield licensees from enforcement actions. Licensees participating in the PHWP will be doing so as part of a Board decision ordering probation or because the physician voluntarily self-referred.

**Comment 48:** CSAP states that the high cost to participate in the PHWP will most likely discourage some physicians from self-referral, creating a barrier to early intervention. CSAP requests the Board waive cost recovery and to require the Board to reimburse cost recovery that has already been paid for physicians that successfully complete the program as a condition of probation. CSAP requests the Board add the following language in **bold** to section 1357.1(h):

Cost recovery amounts assigned to board-mandated participants
disciplined for substance abuse problems shall be expunged upon
successful program completion. Payments to cost recovery assignments
already made by the participant who successfully completes the program
shall be reimbursed.

**Proposed Response to Comment 48:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in Proposed Response to Comment 45.

**Comment 49:** CSAP would like more clarification pertaining to the circumstances and the limit of the authority of the vendor when it comes to imposing practice restrictions.

**Proposed Response to Comment 49:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in Proposed Response to Comment 30.

**Comment 50:** CSAP asked for clarification on whether records required to be retained under section 1357.9 would be subject to disclosure in response to a Public Records Act request.

**Proposed Response to Comment 50:** The Board has reviewed this comment and does not recommend any changes to the language. The vendor is a private entity not subject to the CPRA. Public Records Act requests would have to be directed to the Board. The public's access to public records is controlled by the CPRA under Government Code section 7920.000, et seq. Records that are not authorized to be

withheld under the CPRA are required to be produced. Among other exemptions, records of complaints and investigations are exempt from production pursuant to Government Code section 7923.600, and medical records or similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy, are exempt from production pursuant to Government Code section 7927.700.

**Comment 51:** CSAP requests that the Board add language to section 1357.14 to require audits to be available to the public and participants in the program as indicated in **bold**:

(f) The audit reports referenced in this section shall be provided to the participant upon request. Also, privacy law-compliant redacted audit reports may be made available to the public upon request.

**Proposed Response to Comment 51:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in Proposed Response to Comment 45.

**Comment 52:** CSAP requests that the Board add language to section 1357.9 requiring participants to be notified when the program receives a request for their records as indicated in **bold**:

(g) A participant shall be notified by the program when it receives a request for the participant's records.

**Proposed Response to Comment 52:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in Proposed Response to Comment 46.

 Written Comments and Oral Testimony from Edwin Kim, M.D., on behalf of the Federation of State Physician Health Programs (FSPHP) dated November 14, 2023

**Comment 53:** FSPHP requests that individuals be permitted to seek assistance from the PHWP confidentiality.

**Proposed Response to Comment 53:** The Board has reviewed this comment and does not recommend any changes to the language. Individuals are able to self-refer to the program under the existing language, as required by BPC section 2340.2(d). Their participation in the program will remain confidential so long as they are compliant with the terms and conditions of their monitoring agreement and are not subject to a practice restriction. If the vendor imposes a practice restriction this will be reported to the Board for posting on the licensee's online profile pursuant to proposed section 1357.11, but their participation in the program will not be identified.

**Comment 54:** FSPHP requests that the Board consider expanding the scope of the PHWP to conditions beyond substance use disorders, such as other mental health or

psychiatric disorders that are impairing or potentially impairing, as the program is named a "health and wellness" program.

**Proposed Response to Comment 54:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in Proposed Response to Comment 44.

Comment 55: FSPHP made several comments relating to the cost and funding of the program. FSPHP indicates that the costs for each participant are excessive and unfortunate, and the program is underfunded. Further, FSPHP indicates that struggling physicians cannot bear the weight of the substantial fees of the program, including factoring in the costs for the required audits, without assistance and asks the Board to revisit adequate funding. If costs are not offset for residents, fellows, and unemployed physicians, then this will likely impact vulnerable/underserved populations and may result in continued loss of physician workforce in California. Further, the Board and the program should account for the increased risk of physician suicide, which is exacerbated by loneliness and hopelessness. FSPHP is concerned that the financial burdens of the program in the context of possible license action may severely impede physicians' ability to seek help.

**Proposed Response to Comment 55:** The Board has reviewed this comment and does not recommend any changes to the language. Pursuant to BPC sections 2340.6(a)(6) and 2340.8(c), the individual participants are obligated to pay the costs of their participation in the program. This does not preclude any participants from seeking outside financial assistance to pay for the treatment required by the program, such as with their insurance company, workplace programs, or other resources. As part of the regulatory process, the Board must project the costs associated with implementing the PHWP and approximately how many would be affected annually.

**Comment 56:** FSPHP indicated that the Board should consider including evaluation and treatment resources that have the opportunity for insurance and workplace reimbursements.

**Proposed Response to Comment 56:** The Board has reviewed this comment and does not recommend any changes to the language. The regulatory text does not prevent participants from seeking outside financial assistance to pay for the treatment required by the program, such as with their insurance company, workplace programs, or other resources.

**Comment 57:** FSPHP commented that the anticipated 40-50 referrals annually with no plans for growth is a mistaken projection of prevalence. For a state with one of the highest numbers of actively licensed physicians, the penetrance of the proposed program is grossly underestimated considering the proportion of those who may be suffering.

**Proposed Response to Comment 57:** The Board has reviewed this comment and does not recommend any changes to the language. First, this comment is not directed

to the proposed text. Further, the Board provided an estimate on the number of licensees who may be referred to the program based on its history of enforcement actions involving substance abusing licensees. The Board's estimate does not impact how many participants can be enrolled in the PHWP.

**Comment 58**: FSPHP commented that there is a stated requirement of being out of work for 30 days with reference to this being unpaid. FSPHP suggests alternative language might include the use of medical leave of absence only when indicated and may be paid or unpaid depending on the individual's circumstance.

**Proposed Response to Comment 58:** The Board has reviewed this comment and does not recommend any changes to the language. First, this comment is not directed to the proposed text, but rather the estimated cost impact to a representative private person. The Board indicated that there "may" be income loss, but the Board does not have any jurisdiction over a licensee's use of paid versus unpaid medical leave or how or whether an individual is compensated during any periods of nonpractice.

**Comment 59:** FSPHP stated that early intervention will be lacking because the current proposal appears more aligned with a licensing board monitoring program for substance use disorders for those physicians who are mandated to enroll, and under its current construct, there are limited reasons for physicians to come forward preventively for well-being or wellness.

**Proposed Response to Comment 59:** The Board has reviewed this comment and does not recommend any changes to the language. This comment appears to object to the provisions required by the Uniform Standards, such as the requirement to report violations and practice restrictions. Pursuant to BPC section 2340.2(e), the program is required to comply with the Uniform Standards.

**Comment 60:** FSPHP requests that the Board provide language about how the monitoring vendor will be selected/vetted and requests that language addressing the following issues regarding the vendor be included:

- Requirements for the monitoring vendor to maintain policies and procedures for addressing informed consent, privacy, nondiscrimination, and a process for vetting complaints/appeals.
- A requirement for receiving feedback from participants regarding the vendor and the monitoring practices and for transparency.
- A method for the Board, program, and vendor to address complaints about the monitoring vendor. This should augment the proposed 3-year audits and serve as a continuous platform for participants to provide confidential feedback – both positive and negative, suggestions for improvement, privacy violations, and complaints about the monitoring vendor.

**Proposed Response to Comment 60:** The Board has reviewed this comment and does not recommend any changes to the language. Pursuant to BPC section 2340.4(a), the Board is required to contract for the administration of the PHWP with a private third-

party independent administering entity pursuant to a request for proposals (RFP), Article 4 (commencing with Section 10335) of Chapter 2 of Part 2 of Division 2 of the Public Contract Code. This is a transparent process and ensures that the vendor selected complies with all applicable statutes and regulations and has the expertise, as well as the level of staff necessary, to administer the PHWP. The vendor will be required to report information to the Board consistent with proposed section 1357.13, which will provide insight into the program between audits. Additionally, at a minimum, the data reported will be published annually. Participants and other stakeholders are free to raise concerns about the vendor and any contractor directly with the involved entity or individual or with the Board for review, and this does not require regulatory language.

**Comment 61:** FSPHP requests the Board consider including definitions of licensed supervision when determining drug testing frequency. Specifically, who fits the role of "licensed supervisor" in the documentation that drug testing frequency can be reduced and clarify the meaning of 50% supervision (i.e. in treatment 50% of the time or working with a clinical/educational supervisor 50% in the workplace).

**Proposed Response to Comment 61:** The Board has reviewed this comment and does not recommend any changes to the language. The proposed text amending section 1365.1(c)(3) complies with the Uniform Standards exactly and is clear that the supervision required is supervision during practice. Additionally, a supervisor for a physician under this section could only be a physician. No other type of Board licensee could supervise a physician.

**Comment 62:** FSPHP commented that proposed section 1357.12(d) states that if the Board initiates an investigation, the vendor has three days to notify the Board about whether the physician is in monitoring and compliance status. FSPHP requests that the Board clarify the reporting of non-compliance issues by the vendor to prevent retaliatory or discriminatory reporting and recommends that the Board have thresholds for reporting to include notifying participants which forms of non-compliance require reporting.

**Proposed Response to Comment 62:** The Board has reviewed this comment and does not recommend any changes to the language. The purpose of proposed section 1357.12(d) is to make clear to the vendor that the Board contracts with that upon an inquiry by the Board, the vendor must provide a written response indicating whether a licensee is enrolled in the PHWP pursuant to BPC section 2340.2(d). Major and minor violations, withdrawals, and terminations must be reported to the Board consistent with proposed section 1357.12(a) – (c) to be compliant with the Uniform Standards.

**Comment 63:** FSPHP indicates that most state physician health programs (PHPs) are a resource for self-referring physicians who are seeking assistance for substance use or psychiatric concern. FSPHP states that the current proposal requires the monitoring vendor to report any positive drug testing to the Board indiscriminately, and that this opens an unnecessary and intrusive method of reporting a physician who has self-referred to the PHWP. Furthermore, to account for false positives, environmental contamination, or a medical reason that someone might test positive, when it is not a

return to use, the language should read "confirmed" return to use. FSPHP states that reporting any positive will have huge impacts on willingness to self-refer and could be seen as discriminatory.

**Proposed Response to Comment 63:** The Board has reviewed this comment and does not recommend any changes to the language. BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. A positive biological fluid test is required to be reported to the Board pursuant to proposed section 1357.10(f) as it is a requirement under Uniform Standard #13.

**Comment 64:** FSPHP indicates that the Board should reconsider the requirement for immediate cease of practice for a single positive drug test, without any language about confirmation of return to use or concerns about current impairment, indicating that this could be considered discriminatory and a heavy-weighted approach which does not account for a state PHP's ability to help the Board and the participant navigate a positive test result. FSPHP requests that the Board consider updated language that the monitoring vendor will evaluate the positive test result with other data like testing history, workplace monitor reports, treatment provider reports, or in consultation with an evaluator or medical review officer before deciding for ceasing practice.

**Proposed Response to Comment 64:** The Board has reviewed this comment and does not recommend any changes to the language. BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. The proposed text requires participants to comply with and be tested in accordance with all the requirements set forth in existing regulation section 1361.5(c)(3) which is consistent with the requirements of Uniform Standard #4.

Comment 65: FSPHP states that the reporting requirement of practice restrictions to the Board, and documentation on the public website indiscriminately includes both Board-mandated participants and self-referred participants. FSPHP indicates that this section should specify that practice restrictions imposed by vendor or treatment providers are due to the underlying health condition being monitored or impairment. FSPHP further states that it would be unreasonable that a participant who takes a leave of absence or is recommended for time away from work related to another non-impairing health issue or personal/family health issues will need to be reported. Reporting any restriction, especially in self-referred participants, will further limit the number of participants who self-refer and could be seen as discriminatory.

**Proposed Response to Comment 65:** The Board has reviewed this comment and does not recommend any changes to the language. BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. As explained in the ISOR, pursuant to Uniform Standard #14, the vendor is required to notify the Board of the participant's name; whether the participant's license is restricted or in a non-practice status; and a detailed description of each restriction imposed. The vendor will be required to make this report to the Board within one business day of imposing a practice restriction on a participant, regardless of whether the participant is Board-referred or self-referred so that the Board may alert the public to the practice restriction. To protect the privacy of a

self-referred participant, however, the Board will not indicate that the practice restriction has been imposed by the PHWP.

**Comment 66:** FSPHP states that the Board should consider that required reporting of non-excused missed groups, even in self-referred participants within two business days resulting in disclosure of protected health condition can be inappropriate, because this opens the possibility of a participant's information being exposed when they were merely tending to an emergent family or personal health issue. FSPHP requests that the language be amended to allow the vendor to confirm it was an unexcused absence.

**Proposed Response to Comment 65:** The Board has reviewed this comment and does not recommend any changes to the language. BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Proposed section 1357.12(b) requires the vendor to report each minor violation by a participant as defined in existing section 1361.52(c) to the Board within five business days. This proposed section complies with Uniform Standard #13(1).

**Comment 66:** FSPHP states that nail testing should be a provided option for testing as some participants cannot produce samples for hair testing due to any variety of physiological, social, cultural, or religious reasons.

**Proposed Response to Comment 66:** The Board has reviewed this comment and does not recommend any changes to the language. Proposed section 1357.10(e)(2) requires participants to comply with and be tested in accordance with all the requirements set forth in existing section 1361.5(c)(3). Several options are provided for testing, including urine, blood, breath, or hair.

**Comment 67:** FSPHP states that proposed section 1357.12(b) pertains to Uniform Standard #10 relating to consequences for major and minor violations. FSPHP states that the reporting requirement for minor violations ensures that 100% of self-referred participants will lose their confidential status with the Board, which will increase the likelihood of a licensee with a substance use disorder not seeking help.

**Proposed Response to Comment 67:** The Board has reviewed this comment and does not recommend any changes to the language. BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Proposed section 1357.12(b) complies with the reporting requirement under Uniform Standard #13(1). The PHWP does require strict compliance by self-referred participants to maintain their confidentiality of their participation.

**Comment 68:** FSPHP states that the frequency of testing required under section 1361.5 will benefit the lab and third-party vendors, because of increased revenue, however, there is no basis for this increased rate of testing frequency. FSPHP states that 52-104 tests in the first year seems excessive and will decrease the likelihood of self-referrals, whereas 24-36 tests in years 2-5 seems reasonable. FSPHP further comments that having an informed PHWP, with expertise commensurate with other state-voting members of the Federation of State Physician Health Programs, utilizing

treatment recommendations from a treating entity with expertise in treating physicians is the best way to guide decisions regarding testing frequency.

**Proposed Response to Comment 68:** The Board has reviewed this comment and does not recommend any changes to the language. BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Proposed section 1357.10(e) requires participants to comply with and be tested in accordance with all the requirements set forth in existing section 1361.5(c)(3), which complies with Uniform Standard #4.

**Comment 69:** FSPHP states that the proposed text indicates that references to the "Board" in existing regulation, 16 CCR section 1361.5(c)(1)(A)-(D), shall mean the vendor [for self-referred participants]. Thus, a self-referred participant will only provide notice of their employers and consent to communicate to the vendor, and not the Board. FSPHP indicates that this language describes confidentiality, which is good.

**Proposed Response to Comment 69:** The Board has reviewed this comment and has determined that no change in the proposed text is requested or necessary.

**Comment 70:** FSPHP commented that the proposed text relating to support group meetings (proposed section 1357.10(j)) and worksite monitors (proposed section 1357.10(k)) seems very reasonable and is consistent with best practices.

**Proposed Response to Comment 70:** The Board has reviewed this comment and has determined that no change in the proposed text is requested or necessary.

**Comment 71:** FSPHP commented with regard to proposed sections 1357(i) defining "practice restriction" and 1357.11 regarding the reporting and public disclosure of practice restrictions, that every licensee with a moderate or severe substance use disorder (SUD) diagnosis will likely require residential treatment, requiring cessation of practice. FSPHP states that the mandatory reporting requirements outlined in 1357.11 will further stigmatize addiction and disincentivize self-referrals to the PHWP, which will result in a decrease in referrals and contribute to a higher likelihood of a licensee practicing with an untreated potentially impairing illness.

**Proposed Response to Comment 71:** The Board has reviewed this comment and does not recommend any changes to the language. BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. This proposed section complies with Uniform Standard #14. As explained in the ISOR, to protect the privacy of a self-referred participant the Board will not indicate that the practice restriction has been imposed by the PHWP.

**Comment 72:** FSPHP states that the estimate of participants that will be required to undergo a 30 day in-treatment program is underestimated considering California has more active physicians and the costs associated with group meetings and a worksite monitor is excessive. FSPHP indicated that the costs will make it very difficult to practice medicine and is hopeful that the Board will elect to waive this requirement when indicated.

**Proposed Response to Comment 71:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in Proposed Responses to Comments 54 and 57.

 Oral Testimony from Rebecca Marcus speaking on behalf of the Consumer Protection Policy Center (CPPC), UC San Diego on November 14, 2023

**Comment 72:** Rebecca Marcus on behalf of CPPC requests the Board reject the proposed regulations to create a Physician Health and Wellness Program because they are unclear and inconsistent with the Uniform Standards, as well as unauthorized and duplicative of other Board regulations. Rebecca Marcus referred the Board to CPPC's letter dated November 13, 2023, which outlines in detail their comments regarding the PHWP.

**Proposed Response to Comment 72:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in Proposed Responses to Comments 26 - 32.

 Oral Testimony from Alka Airy, Volunteer with Consumer Watchdog, on November 14, 2023

**Comment 73**: Alka Airy commented that the Board must follow the Uniform Standards and the proposed regulations do not clearly state how the Uniform Standards apply, when they apply, and the consequences when the Uniform Standards are violated. Alka Airy requests that the Board cite the Uniform Standards in each regulation and the consequences licensees will face when there is a violation.

**Proposed Response to Comment 73:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in Proposed Response to Comments 2 and 23.

• Oral Testimony from Maria Ibarra-Navarette, Volunteer with Consumer Watchdog on November 14, 2023

**Comment 74:** Maria Ibarra-Navarette indicated that the Board must follow the Uniform Standards and the proposed regulations do not clearly cite them. Maria Ibarra-Navarette requests that the Board cite the Uniform Standards in each regulation and the consequences licensees will face when there is a violation.

**Proposed Response to Comment 74:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in Proposed Response to Comments 2 and 23.

## • Oral Testimony from Kimberly Turbin, Volunteer with Consumer Watchdog on November 14, 2023

**Comment 75:** Kimberly Turbin indicated that the Board must follow the Uniform Standards and the proposed regulations do not clearly cite them. Further, Kimberly Turbin stated that is not enough to cite the Uniform Standards in the beginning of the proposed section and requests that the Board cite the Uniform Standards in each regulation and the consequences licensees will face when there is a violation.

**Proposed Response to Comment 75:** The Board has reviewed this comment and does not recommend any changes to the language for the reasons set forth in Proposed Response to Comments 2 and 23.