

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: October 17, 2017
 ATTENTION: Members, Medical Board of California
 SUBJECT: Physician and Surgeon Health and Wellness Program
 Proposed Regulations
 FROM: Kerrie Webb, Senior Staff Counsel

REQUESTED ACTION:

After review and consideration of the attached proposed regulations for the Physician and Surgeon Health and Wellness Program (PHWP), make a motion to authorize staff to do the following:

- 1) Submit the proposed rulemaking package to the Department of Consumer Affairs (DCA) and the Business, Consumer Services and Housing Agency (Agency);
- 2) Upon DCA and Agency approval, submit the rulemaking package to the Office of Administrative Law (OAL) to formally notice the proposed regulations and schedule a hearing on the rulemaking to add Title 16, Division 13, Chapter 2, Article 2, of the California Code of Regulations (CCR), sections 1357.10, 1357.11, 1357.12, 1357.13, 1357.14, 1357.15, and 1357.16; and
- 3) Make non-substantive changes to the language, as needed.

BACKGROUND:

Senate Bill (SB) 1177 (Galgiani, Chapter 591, Statutes of 2016), authorized the Medical Board of California (Board) to establish a PHWP with the goal of providing early identification of, and appropriate interventions to support rehabilitation from, substance abuse to ensure physicians remain able to practice medicine in a manner that will not endanger the public and will maintain the integrity of the medical profession. This bill, under Business and Professions Code (B&P) section 2340.2(e) requires the PHWP to comply with the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees (Uniform Standards) as adopted by the Substance Abuse Coordination Committee (SACC) of DCA pursuant to B&P section 315.

On October 28, 2016, the Board voted to move forward with establishing a PHWP. Board staff held an interested parties meeting on January 11, 2017, to review the law and the Uniform Standards and to discuss ideas for regulatory language.

On October 4, 2017, Board staff held a second interested parties meeting to review the proposed regulatory language and obtain feedback. The attached language incorporates several changes requested by the interested parties at the meeting and through written comment, including additional definitions, bolstering needed qualifications for contractors, specifying the timeframe for removing practice restrictions from the website once they are lifted, and others.

Some interested parties sought changes that deviated from the Uniform Standards, and were not included in these proposed regulations. Additionally, an interested party requested a committee be formally established through regulation to review the work of the PHWP. The Board may direct staff to draft language to create such a committee now through regulation, or the Board may create a committee at a later time by approval of the Board President or through the rulemaking process.

Of note, SB 796 (Hill, Chapter 600, Statutes of 2017), requires DCA to reconvene the SACC by January 1, 2019, to review the existing criteria for Uniform Standard #4 dealing with biological fluid testing to determine whether it should be updated to reflect recent developments in testing research and technology. If changes are made to the Uniform Standards, then the proposed regulations will be modified accordingly.

Once these regulations are approved by OAL and filed with the Secretary of State, Board staff will seek bids for the vendor, and will then draft regulations to set the fees for participants in the PHWP.

STAFF RECOMMENDATION:

Staff recommends the Board approve the proposed regulations, 16 CCR sections 1357.10 through 1357.16, authorize staff to proceed through the rulemaking process, and notice the modified language for a 45-day comment period and hearing upon DCA and Agency approval. Staff further recommends the Board authorize staff to make any non-substantive changes to the proposed language during the rulemaking process, as needed.

Draft Regulations for the Physician and Surgeon Health and Wellness Program

Pursuant to SB 1177

Article 2. Physician and Surgeon Health and Wellness Program

1357.10. Definitions.

As used in this article:

- (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 health provider used to determine:
 - (1) whether the participant has a substance abuse problem;
 - (2) whether the participant is a threat to himself or herself or others; and
 - (3) recommendations relating to the participant's treatment, rehabilitation, and/or the participant's ability to practice medicine safely.
- (c) "Contractor" includes a contractor or a subcontractor who contracts to perform services for a vendor, including but not limited to medical or mental health, or other service providers.
- (d) "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.
- (e) "Licensee" means a California licensed physician and surgeon.
- (f) "Participant" means a California licensed physician and surgeon enrolled in the Program pursuant to a signed agreement with the Program, regardless of whether he or she enrolled as Board-referral pursuant to a condition of probation or as a self-referral.
- (g) "Practice restriction" means a restriction from practicing medicine for any period of time or a limitation on any of the following:
 - (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.
- (h) "Program" means the Physician and Surgeon Health and Wellness Program authorized pursuant to Article 14 commencing with Section 2340 of the code.
- (i) "Substance abuse problem" includes but is not limited to such terms as substance abuse disorder and addiction.
- (j) "Vendor" means the entity contracted with the Board to perform services required to administer the Program or its designee.

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

1357.11. Requirements for the Physician and Surgeon Health and Wellness Program Vendor

A vendor under this article shall comply with the following requirements:

- (a) General Vendor Requirements:

- (1) The vendor shall attest in writing to its understanding and agreement to comply with Article 14 commencing with section 2340 of the code and applicable regulations.
- (2) The vendor shall have a minimum of five (5) years' experience in monitoring and rehabilitating health professionals with substance abuse problems.
- (3) The vendor shall contract with a physician and surgeon licensed in California with a minimum of five (5) years' experience in treating addiction to serve as the medical director.
- (4) The vendor shall develop and implement a plan approved by the Board to provide outreach and educational activities to interested parties such as medical students, medical residents, physicians and surgeons, and their family members; medical schools; residency programs; professional associations; hospitals; medical groups; licensing authorities; legislators; employee assistance programs; mental health providers; substance abuse treatment providers; malpractice insurers; managed care plans; consumer groups; and the general public.

Educational techniques/methodologies may include, but not be limited to: lectures; brochures; media; websites; publications/articles; newsletters; display booths; and inclusion of information on renewal applications and on malpractice insurance forms.

- (5) The vendor shall not have a conflict of interest with contractors used for referrals.
- (6) The vendor is fully responsible for the acts and omissions of its contractors and of persons either directly or indirectly employed by any of them. No contract or subcontract shall relieve the vendor of its responsibilities and obligations. All statutes, regulations, and agreements between the Board and the vendor apply to all of the vendor's contractors.
- (7) If a contractor fails to provide effective or timely services as required by statute, regulation, or contractual agreement, the vendor will terminate services of said contractor within 30 business days of notification of failure to provide adequate services.
- (8) The vendor shall notify the Board within five (5) business days of termination of a contractor.
- (9) The vendor shall ensure that before each participant enrolls in the Program, the participant signs an acknowledgment form to be maintained in his or her Program file that includes but is not limited to the following information:
 - a. Participation in the Program will not shield the participant from disciplinary action by the Board, and termination or withdrawal from the Program, and major and minor violations as defined in section 1361.52(a) and (c), respectively, will be reported to the Board;
 - b. The vendor shall inform the Board of any practice restrictions placed on the participant, and the Board shall post the practice restriction on the participant's

profile on the Board's website without revealing the individual's participation in the Program, as required by section 1357.12; and

- c. The participant shall pay all costs associated with participation in the Program, including, but not limited to: Program costs; clinical diagnostic evaluations; biological fluid testing; in-patient or out-patient care; medical or psychological treatment; support group meetings; and worksite monitors, as applicable.

(b) Clinical Diagnostic Evaluation: If the vendor or Board requires a participant to undergo a clinical diagnostic evaluation, the following requirements apply:

- (1) The clinical diagnostic evaluation shall be conducted by a licensed physician and surgeon who holds a valid, unrestricted license; has three (3) years' experience in providing evaluations of physicians and surgeons with substance abuse disorders; and is approved by the Board as an evaluator.
- (2) The clinical diagnostic evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations.
- (3) The evaluator shall not have a current or former financial, personal, or business relationship with the participant within the last five (5) years. The evaluator shall provide an objective, unbiased, and independent evaluation.
- (4) The clinical diagnostic evaluation report shall set forth, in the evaluator's opinion, the following:
 - a. Whether the participant has a substance abuse problem;
 - b. Whether the participant is a threat to himself or herself or others; and
 - c. Recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the participant's rehabilitation and ability to practice safely. If the evaluator determines during the evaluation process that a participant is a threat to himself or herself or others, the evaluator shall notify the vendor and the Board within 24 hours of such a determination.
- (5) For all evaluations, a final written report shall be provided to the vendor and the Board for Board-referred participants, or to the vendor for self-referred participants, no later than ten (10) days from the date the evaluator is assigned the matter. If the evaluator requests additional information or time to complete the evaluation and report, an extension may be granted, but shall not exceed 30 days from the date the evaluator was originally assigned the matter.

(c) Practice Restrictions Pending Clinical Diagnosis Evaluation: If the vendor or Board requires a participant to undergo a clinical diagnostic evaluation, then the following requirements apply:

- (1) The participant shall cease practice pending the results of the clinical diagnostic evaluation and review of the results by the vendor and the Board for Board-referred

participants, or by the vendor for self-referred participants.

- (2) While awaiting the results of the clinical diagnostic evaluation, the participant shall undergo random biological fluid testing at least two (2) times per week.
- (3) The Board for Board-referred participants, or the vendor for self-referred participants shall review the clinical diagnostic evaluation report within five (5) business days of receipt to determine whether the participant is safe to return to either part-time or full-time practice and what restrictions or recommendations shall be imposed on the participant based on the recommendations made by the evaluator, if applicable. The following criteria shall be considered when determining whether or not the participant is safe to return to either part-time or fulltime practice:
 - a. The participant's license type;
 - b. The participant's history;
 - c. The participant's documented length of sobriety/time that has elapsed since substance use;
 - d. The participant's scope and pattern of use;
 - e. The participant's treatment history;
 - f. The participant's medical history and current medical condition;
 - g. The nature, duration and severity of the participant's substance abuse; and
 - h. Whether the participant is a threat to himself or herself or the public.

- (4) No participant shall be returned to practice until he or she has at least 30 days of negative biological fluid tests or biological fluid tests indicating that the participant has not used, consumed, ingested, or administered to himself or herself a prohibited substance, as defined in section 1361.51(e).

(d) Employer Notification: If the participant has an employer, the participant shall provide to the vendor the names, physical addresses, mailing addresses, and telephone numbers of all employers and shall give specific, written consent that the participant authorizes the vendor and the employers to communicate regarding the participant's work status, performance, and monitoring.

(e) Biological Fluid Testing:

- (1) The vendor shall require participants to abstain from the use, consumption, ingestion, or administration of prohibited substances, as defined in section 1361.51(e).
- (2) The vendor shall require biological fluid testing of participants.
- (3) For the purposes of the Program, the terms "biological fluid testing" and "testing" mean the acquisition and chemical analysis of a participant's urine, blood, breath, or hair.
- (4) The vendor may require a participant to undergo a biological fluid test on any day, at any time, including weekends and holidays. Additionally, the participant shall be subject to 52-104 random tests per year within the first year of enrollment in the Program, and 36-104 random tests per year during the second year of enrollment and for the duration

of the enrollment 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.

- (5) Nothing precludes the vendor from increasing the number of random tests to the first-year level of frequency for any reason, including, but not limited to, if the vendor finds or has suspicion that a participant has committed a violation of the testing program or has committed a violation as identified in section 1361.52(a), in addition to reporting the participant to the Board, and imposing any other requirements that may be warranted.
- (6) 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 vendor.
- (7) The participant shall be required to make daily contact with the vendor to determine if biological fluid testing is required. The participant shall be tested on the date of the notification as directed by the vendor.
- (8) The participant shall be provided a list of approved testing sites, and may test at any approved site capable of performing the type of test ordered for that day. Prior to changing testing locations to a site not included on this list for any reason, including during vacation or other travel, alternative testing locations must be approved by the vendor and meet the requirements set forth in subsection (g). Participants shall not be excused from testing during travel, including during vacations.
- (9) Exceptions to Biological Fluid Testing Frequency Schedule:
 - a. Previous Testing Orders/Sobriety: In cases where the vendor has evidence that a participant has been enrolled in a treatment or monitoring program requiring random testing prior to being subject to testing by the vendor, the vendor may give consideration to that testing in altering the vendor's own testing schedule so that the combined testing is equivalent to the requirements of this section.
 - b. Violation(s) Outside of Employment: A participant whose license is placed on probation by the Board or who self-referred following 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 participant'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.
 - c. Not Employed in Health Care Field: The vendor may reduce the testing frequency to a minimum of 12 times per year for any participant 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 participant wants to return to practice or work in a health care field, the participant shall notify and secure the approval of the vendor. Prior to returning to any health care employment, the participant shall be required to test at the first-year testing frequency requirement for a period of at least 60 days. At such time the participant returns to employment in a health care field, if the participant has not

previously met the first-year testing frequency requirement, the participant 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.

- d. Tolling: With Board approval, the vendor may postpone all testing for any participant whose probation is placed in a tolling status while the participant is not residing in California, provided the overall length of the probationary period is also tolled. The participant shall notify the vendor upon the participant's return to California and shall be subject to biological fluid testing as provided in this section. If the participant returns to employment in a health care field and has not previously met the 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.

Tolling is not an option for a self-referred participant so long as he or she has a license to practice in a health care field in California. A self-referred participant who is moving out of state, however, may transfer monitoring and care to a program in the new location upon the vendor's approval. The self-referred participant shall have the out-of-state program automatically forward testing results and compliance reports to the vendor. Any major violation as defined in section 1361.52(a) or minor violation as defined in section 1361.52(c) shall be reported to the Board. Prior to returning to the State of California to practice in a health care field, the self-referred participant shall re-enter into a contract for monitoring and care with the vendor. Upon returning to the State of California to practice in a health care field, if the self-referred participant has not previously met the first-year testing frequency requirements, he or she 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.

- e. 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 vendor, but shall not be less than 24 times per year.
- (f) Positive Biological Fluid Tests: When a participant tests positive for a prohibited substance, the vendor shall take the following actions:
- (1) Notify the Board within one (1) business day of receiving the results;
 - (2) Notify the participant that he or she must cease practice immediately;
 - (3) Notify the participant's employer, if any, and worksite monitor, if any, that the participant may not practice until further notice.
- (g) Specimen Collection, Testing Locations, and Laboratories: A vendor's contractors that provide specimen collection, testing locations, or laboratory services shall meet the following requirements:
- (1) Specimen collectors shall either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the United States Department of Transportation.

- (2) Specimen collectors shall conform to the current United States Department of Transportation Specimen Collection Guidelines.
- (3) Specimen collectors shall observe the collection of testing specimens.
- (4) Testing locations shall comply with the Urine Specimen Collection Guidelines published by the United States Department of Transportation without regard to the type of test administered.
- (5) Testing locations shall possess all the materials, equipment, and technical expertise necessary in order to test every participant for which it is responsible on any day of the week.
- (6) Testing locations shall be able to scientifically test for urine, blood, breath, and hair specimens for the detection of alcohol and illegal and controlled substances.
- (7) The contractor's testing sites must be located throughout California.
- (8) The contractor must have an automated 24-hour toll-free telephone system and/or a secure on-line computer database that allows the participant to check in daily for testing.
- (9) Testing locations shall submit a specimen to a laboratory within one (1) business day of receipt and all specimens collected shall be handled pursuant to chain of custody procedures. The laboratory shall process and analyze the specimen and provide legally defensible test results to the Board within seven (7) business days of receipt of the specimen. The Board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.
- (10) Laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.
- (11) The contractor must have a secure, HIPAA-compliant website or computer system to allow staff access to drug test results and compliance reporting information for Board-referred participants that is available 24 hours a day.
- (12) The contractor shall employ or contract with toxicologists that are licensed physicians and surgeons and have knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate laboratory biological fluid test results, medical histories, and any other information relevant to biomedical information.
- (13) A toxicology screen will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.
- (14) The contractor shall undergo training on the requirements for biological fluid testing mandated by the Program.

- (h) Type of Treatment: In determining whether inpatient, outpatient, or other type of treatment is necessary, the vendor and its contractors shall consider the following criteria:
- (1) Recommendation of the clinical diagnostic evaluation;
 - (2) License type;
 - (3) Participant's history;
 - (4) Documented length of sobriety/time that has elapsed since substance 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 himself or herself or the public.
- (i) Treatment Providers: A vendor's contractors providing treatment shall meet the following requirements:
- (1) Licensure and/or accreditation by appropriate regulatory agencies;
 - (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;
 - (5) Treatment planning involving a multidisciplinary approach and specific aftercare plans;
 - (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.
- (j) Support Group Meeting Facilitators: If the vendor or Board requires a participant to participate in support group meetings, the following shall apply:
- (1) When determining the frequency of group support meetings to be attended, the vendor shall give consideration to the following:
 - a. The participant's history;
 - b. The documented length of sobriety/time that has elapsed since substance use;
 - c. The recommendation of the clinical evaluator;
 - d. The scope and pattern of use;
 - e. The participant's treatment history; and
 - f. The nature, duration, and severity of substance abuse.
 - (2) The facilitator of a group support meeting shall conform to the following requirements:
 - a. He or she shall have a minimum of three (3) years' experience in the treatment and rehabilitation of health professionals with substance abuse problems, and shall be licensed or certified by the state or nationally certified organizations.
 - b. He or she shall ensure that group meetings do not routinely exceed 14 participants.

- c. He or she shall not have a current or former financial, personal, or business relationship with the participant within the last five (5) years. A participant's previous participation in a support group meeting led by the same facilitator does not constitute a current or former financial, personal, or business relationship.
 - d. Upon request, he or she shall provide to the vendor and Board for Board-referred participants, or to the vendor for self-referred participants, a signed document showing the participant's name, the group name, the date and location of the meeting, the participant's attendance, and the participant's level of participation and progress.
 - e. He or she shall report a participant's unexcused absence to the vendor and Board within 24 hours.
- (k) Worksite Monitors: If the vendor or Board requires a participant to have a worksite monitor, the vendor shall ensure that each worksite monitor meets the following qualifications and will comply with the following requirements:
- (1) The worksite monitor shall not have had a financial, personal, or familial relationship with the participant, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the vendor and Board for Board-referred participants, or to the vendor for self-referred participants. If it is impractical for anyone but the participant's employer to serve as the worksite monitor, this requirement may be waived by the Board for Board-referred participants, or by the vendor for self-referred participants; however, under no circumstances shall a participant's worksite monitor be an employee of the participant.
 - (2) The monitor shall be a licensed physician and surgeon, be another health care professional if no licensed physician and surgeon, or, as approved by the Board for Board-referred participants, or by the vendor for self-referred participants, be a person in a position of authority who is capable of monitoring the participant at work.
 - (3) The monitor shall have an active unrestricted license, with no disciplinary action within the last five (5) years.
 - (4) The monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the participant's disciplinary order and/or contract and agrees to monitor the participant as set forth by the vendor or the Board.
 - (5) The monitor must adhere to the following required methods of monitoring the participant:
 - a. Have face-to-face contact with the participant in the work environment on a frequent basis as determined by the Board for Board-referred participants, or by the vendor for self-referred participants, at least once per week.
 - b. Interview other staff in the office regarding the participant's behavior, if applicable.
 - c. Review the participant's work attendance.
 - (6) Any suspected substance abuse must be verbally reported to the vendor, participant's employer, and, if the participant was Board-referred, to the Board, within one (1) business day of occurrence. If the occurrence is not during normal business hours for

any of the above entities, the verbal report must be within one (1) hour of the entity's next business day. A written report shall be submitted to each of the above entities as required within 48 hours of the suspected substance abuse. The written report shall contain the following information:

- a. The participant's name;
- b. The participant's license number;
- c. The worksite monitor's name and signature;
- d. The worksite monitor's license number;
- e. The worksite location(s);
- f. The name(s) of worksite staff interviewed, if applicable;
- g. A description of the circumstances leading the monitor to suspect substance abuse.

(7) The worksite monitor shall complete and submit a written report monthly to the vendor and the Board for Board-referred participants, or to the vendor for self-referred participants, or as often as directed by the vendor or Board. The report shall include:

- b. The participant's name;
- c. The participant's license number;
- d. The worksite monitor's name and signature;
- e. The worksite monitor's license number;
- f. The worksite location(s);
- g. The dates the participant had face-to-face contact with the monitor;
- h. The name(s) of staff interviewed, if applicable;
- i. An attendance report;
- j. A description of any change in the participant's behavior and/or personal habits;
- k. Any indicators that can lead to suspected substance abuse.

(8) If the worksite monitor resigns or is no longer available, participant shall, within five (5) calendar days of such resignation or unavailability, submit to the vendor and the Board for Board-referred participants, or to the vendor for self-referred participants, for prior approval the name of the person(s) who is qualified and willing to assume that responsibility within 15 calendar days. If the participant fails to obtain approval of a replacement monitor within 30 calendar days of the resignation or unavailability of the worksite monitor, the participant shall receive a notification from the vendor or Board to cease the practice of medicine within three (3) calendar days after being so notified. The participant shall cease the practice of medicine until a replacement worksite monitor is approved and assumes monitoring responsibilities, and the participant is notified in writing from the vendor or the Board that he or she may resume the practice of medicine.

(I) Return of Participant to Full-Time Practice: If participant has been restricted from full-time practice, the vendor shall ensure the participant meets the following criteria prior to returning to full-time practice:

- (1) Demonstrated sustained compliance with current recovery program;
- (2) Demonstrated ability to practice safely as evidenced by current worksite reports, evaluations, and any other information relating to the participant's substance abuse;

- (3) At least six (6) months of negative biological fluid tests or biological fluid tests indicating that the participant has not used, consumed, ingested, or administered to himself or herself a prohibited substance, as defined in section 1361.51(e);
- (4) Two positive worksite monitor reports; and
- (5) Complete compliance with other Program requirements.

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.

1357.12. Report and Public Disclosure of Practice Restrictions for Participants

If a vendor imposes a practice restriction on a participant, the vendor shall report to the Board, 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 being notified that the practice restriction has been lifted.

Note: Authority cited: Sections 2018 and 2340, 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. Reports of Participant Violations, Withdrawals, and Terminations to the Board; Inquiries by the Board

- (a) The vendor shall report to the Board each major violation by a participant, as defined in section 1361.52(a), within one (1) business day, 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 to the Board each minor violation by a participant, as defined in section 1361.52(c) within five (5) business days, 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 to the Board any participant who withdraws or is terminated from the Program within one (1) business day, 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 indicating whether the licensee is a participant in the Program, and if so, the

date the licensee enrolled in the Program, the services being provided to the licensee, and whether the licensee is compliant with the Program.

Note: Authority cited: Sections 2018 and 2340, 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. Vendor Communication with the Board; Annual Reports

- (a) On a periodic basis, whenever requested by the Board, and no less than quarterly to coincide with presentations at the Board’s regularly-scheduled Board meetings, the vendor shall report 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 participant while 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 deviation from the standard of care established by admission or Board decision following an accusation;
 - (10) The number and types of reports filed with the Board pursuant to section **1357.13**;
 - (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 (i.e., 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. At

each educational event provided by the vendor, attendees shall be asked to complete an evaluation of the event and speaker(s), and the evaluation results and comments shall be reported to the Board;

- (14) An accounting of all amounts collected, expenses incurred, and amounts disbursed and for what purposes; and
- (15) Any other data requested in writing by the Board and available to the vendor.
- (b) With regard to subsections (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 (i.e., cocaine, alcohol, Demerol, etc.).
- (c) On a yearly basis, by a date set by the Board, the vendor shall provide all of the data identified in subsections (a) and (b) to the Board for inclusion in the Board's annual report.

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

1357.15. External Independent Audits

- (a) At least once every three (3) years, or at any time requested by the Board, an external, independent audit shall be conducted by a qualified, independent reviewer or review team from outside the department with no real or apparent conflict of interest with 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 be approved in advance by the Board, and consist of individuals who are competent in the professional practice of internal auditing and assessment processes and 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 financial status and performance in adhering to the statutes and regulations applicable to the Program. The auditor must provide a report of his or her findings to the Board by June 30 of each three (3) year cycle. The report shall not identify participants by name, but shall identify any material inadequacies, deficiencies, irregularities, or other noncompliance with the terms of the vendor's treatment or monitoring services that would 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 Board shall respond to the findings in the audit report in writing no later than September 1 of each three (3) year cycle. In its response, if deficiencies were identified in the audit report, 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 approved by the Board, identifying how

each deficiency will be addressed and in what time period. The vendor shall not be given longer than 60 days to cure a deficiency.

- (d) Failure of the vendor to cure all deficiencies within 60 days shall subject the vendor to termination. Termination of the vendor shall be in the sole discretion of the Board.
- (e) 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.

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.

1357.16. Maintenance of Records

The vendor shall maintain the following records for each participant indefinitely:

- (a) All intake reports and case analyses;
- (b) All agreements and amendments thereto;
- (c) All correspondence with the Board;
- (d) All correspondence with the participant;
- (e) All correspondence with contractors;
- (f) All file notes, laboratory test results, and incident reports;
- (g) Other records as required by the Board, and set forth in the contract.

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.