

DEPARTMENT OF CONSUMER AFFAIRS

TITLE 16. MEDICAL BOARD OF CALIFORNIA

PHYSICIAN AND SURGEON HEALTH AND WELLNESS PROGRAM

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing has been scheduled for this proposed action.

Subject Matter of Proposed Regulations: Physician and Surgeon Health and Wellness Program

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

Background and Statement of the Problem

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 a Physician and Surgeon Health and Wellness Program (PHWP) with the goal of providing early identification of, and appropriate interventions, to support rehabilitation from substance abuse. The purpose of 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: This current proposed rulemaking does not address the issue of fees for participants in the PHWP. The Board will move forward with proposed regulations to set fees only once the proposed regulations in this current rulemaking are adopted, and

the vendor for the PHWP is selected.)

This proposed rulemaking is necessary because the statutory sections authorizing the PHWP are too vague to implement the program without further defining them through regulation.

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

Anticipated Benefits

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

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

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

Specific Purpose of Proposed Changes, Anticipated Benefits, and Rationale:

1. Change the Title of Article 2 of Chapter 2 of Division 13 of Title 16 of the CCR from “Impaired Physician Program” to “Physician and Surgeon Health and Wellness Program.”

Purpose: The purpose of changing the title of Article 2 of Chapter 2 of Division 13 of Title 16 of the CCR from “Impaired Physician Program” to “Physician and Surgeon Health and Wellness Program” is to update the language to reflect existing law authorizing the PHWP under BPC section 2340.

Anticipated Benefits: The Board anticipates this change in title will aid interested parties in easily finding all of the regulations applicable to the PHWP and will improve clarity by eliminating the reference to the defunct Impaired Physician Program.

Rationale: The Board no longer operates the “Impaired Physician Program,” which was discontinued as of July 1, 2008. Consequently, it is necessary to update this title to indicate that this article contains the regulations for the PHWP. The statutes authorizing the regulations for the “Impaired Physician Program” former BPC sections 2340 through 2356 were repealed as of January 1, 2009, by the terms of BPC section 2358 (repealed by its own terms).

2. Amend 16 CCR section 1357

Amend section 1357(a)

Purpose: The purpose of amending section 1357(a) is to delete the old definition of “Program” relating to the Board’s defunct impaired physician diversion program and amend subdivision (a) to define “Board” as meaning the Medical Board of California or its designee.

Anticipated Benefits: The Board anticipates that interested parties will benefit from the elimination of outdated references to the Board’s defunct diversion program and the addition of a definition of “Board” that is necessary for the successful implementation of the PHWP.

Rationale: These proposed amendments are necessary to eliminate a definition relating to the Board’s obsolete diversion program and to improve the implementation of the PHWP. The existing definition of “Board” in regulation at 16 CCR section 1300.4(b) encompasses only the Medical Board of California. Since “Board” is used throughout this article [and in the Uniform Standards, adopted in article 2, section 1361.5], this amendment will make it clear that in connection with the PHWP “Board” means the Medical Board of California or its designee.

Amend section 1357(b)

Purpose: The purpose of amending section 1357(b) is to delete the old definition of “Committee” relating to the Board’s defunct impaired physician diversion program and amend subdivision (b) to define “Clinical Diagnostic Evaluation,” which is an evaluation pertinent to the PHWP.

Anticipated Benefits: The Board anticipates that interested parties will benefit by eliminating outdated references to the Board’s defunct diversion program, and adding the definition for “clinical diagnostic evaluation,” which is a term used in the PHWP regulations.

Rationale: This proposed amendment is necessary to eliminate a definition relating to the Board’s obsolete diversion program and to make this section applicable to the PHWP. Since “clinical diagnostic evaluation” is used in the PHWP, this definition will provide clarity for what the term means. The definition clarifies that a clinical diagnostic evaluation is performed by a licensed physician and surgeon. This is necessary, because the PHWP will rely on the evaluation findings to make decisions for eligibility to participate in the program, and what kind of support and treatment are necessary for the participant. Consequently, the evaluation must be conducted by a licensed physician and surgeon who can make a diagnosis and recommendations for treatment, including for any medications.

Under section 1357(b)(1), the clinical diagnostic evaluation includes exams by a licensed physician and surgeon to determine whether the participant has a substance abuse problem. Participants must have a substance abuse problem to be part of the PHWP, as this program is not authorized to assist or monitor physicians with other mental or physical conditions who do not have a substance abuse problem.

Under section 1357(b)(2), the clinical diagnostic evaluation includes exams by a licensed physician and surgeon to determine whether the participant is a threat to themselves or others. This information is necessary as it will assist the PHWP in determining the type of treatment, practice restrictions, monitoring, and support necessary to protect the public and rehabilitate the participant.

Under section 1357(b)(3), the clinical diagnostic evaluation includes exams by a licensed physician and surgeon to determine recommendations relating to the participant’s treatment, rehabilitation, and/or ability practice medicine safely. This information is necessary as it will assist the PHWP in determining the type of treatment, practice restrictions, monitoring, and support necessary to protect the public and rehabilitate the participant.

Add section 1357(c)

Purpose: The purpose of adding section 1357(c) is to provide a definition for “conflict of interest” in the context of the PHWP.

Anticipated Benefits: The Board anticipates that interested parties will benefit from a specific definition for the meaning of “conflict of interest” relevant to the PHWP.

Rationale: This proposed amendment is necessary to provide a definition for “conflict of interest,” as it is a term that is used in the PHWP 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 an individual to render impartial and unbiased reports. Work done as part of the PHWP must be unbiased to be reliable and to further the Board’s mission of consumer protection and rehabilitation of the licensee.

Add section 1357(d)

Purpose: The purpose of adding section 1357(d) is to provide a definition for “contractor” in the context of the PHWP.

Anticipated Benefits: The Board anticipates that interested parties will benefit from a specific definition for the meaning of “contractor” relevant to the PHWP.

Rationale: This proposed amendment is necessary to provide a definition for “contractor,” as it is a term that is used in the PHWP to identify entities and individuals performing services for the vendor as part of the PHWP, including medical, mental health, laboratory, or other service providers. The definition for “contractor” makes it clear that this term includes “subcontractors.”

Add section 1357(e)

Purpose: The purpose of adding section 1357(e) is to provide a definition for “employer” in the context of the PHWP.

Anticipated Benefits: The Board anticipates that interested parties will benefit from a specific definition for the meaning of “employer” relevant to the PHWP.

Rationale: This proposed amendment is necessary to provide a definition for “employer,” as it applies to participants in the PHWP. In this context, “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. This definition is necessary, because in some practice settings, participants may not be directly employed by the facility, but, instead, may be independent contractors who have

a supervisor, chief of staff, health or wellbeing committee chair, or the equivalent. As part of participating in the PHWP, if the participant has an employer, as defined herein, the participant will have to comply with the notification and consent requirements set forth in 16 CCR section 1361.5(c)(2).

Add section 1357(f)

Purpose: The purpose of adding section 1357(f) is to provide a definition for “full-time practice” in the context of the PHWP.

Anticipated Benefits: The Board anticipates that interested parties will benefit from a specific definition for the meaning of “full-time practice” relevant to the PHWP.

Rationale: This proposed amendment is necessary to provide a definition for “full-time practice,” as it applies to participants in the PHWP. In this context, “full-time practice” means the licensee is not subject to any practice restriction imposed by the program or the Board. The definition provides clarity that this term does not require the licensee to work a certain number of hours for the term to be applicable. Under this definition, the licensee is free to determine how many hours to work without a limitation required by the program or the Board.

Add section 1357(g)

Purpose: The purpose of adding section 1357(g) is to provide a definition for “licensee” in the context of the PHWP.

Anticipated Benefits: The Board anticipates that interested parties will benefit from a specific definition for the meaning of “licensee” relevant to the PHWP.

Rationale: This proposed amendment is necessary to provide a definition for “licensee” as it applies to the PHWP. In this context, “licensee” means a California licensed physician and surgeon or a holder of a California physician and surgeon postgraduate training license. The definition provides clarity that the term “licensee” applies to both physician and surgeon licensees and physician and surgeon postgraduate training licensees, as both of these license types may participate in the PHWP.

Add section 1357(h)

Purpose: The purpose of adding section 1357(h) is to provide a definition for “participant” in the context of the PHWP.

Anticipated Benefits: The Board anticipates that interested parties will benefit from a specific definition for the meaning of “participant” relevant to the PHWP.

Rationale: This proposed amendment is necessary to provide a definition for “participant,” as it applies to the PHWP. In this context, “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. The definition provides clarity that the term “participant” requires the person to be a licensee who is enrolled in the program and applies to both Board-referred and self-referred licensees.

Add section 1357(i)

Purpose: The purpose of adding section 1357(i) is to provide a definition for “practice restriction” in the context of the PHWP.

Anticipated Benefits: The Board anticipates that interested parties will benefit from a specific definition for the meaning of “practice restriction” relevant to the PHWP.

Rationale: This proposed amendment is necessary to provide a definition for “practice restriction,” as it applies to the PHWP. In this context, “practice restriction” 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. This definition provides clarity as to what falls within the definition of a practice restriction.

Add section 1357(j)

Purpose: The purpose of adding section 1357(j) is to provide a definition for “program” in the context of the PHWP.

Anticipated Benefits: The Board anticipates that interested parties will benefit from a specific definition for the meaning of the word “program” relevant to the PHWP.

Rationale: This proposed amendment is necessary to provide a definition for the word “program,” as it applies to the PHWP. In this context, “program” means the Physician and Surgeon Health and Wellness Program authorized pursuant to Article 14 commencing with Section 2340 of the code. The word “program” is used in the PHWP and throughout these proposed PHWP regulations, and this definition provides clarity that it means the PHWP.

Add section 1357(k)

Purpose: The purpose of adding section 1357(k) is to provide a definition for “vendor” in the context of the PHWP.

Anticipated Benefits: The Board anticipates that interested parties will benefit from a specific definition for the meaning of the word “vendor” relevant to the PHWP.

Rationale: This proposed amendment is necessary to provide a definition for the word “vendor,” as it applies to the PHWP. In this context, “vendor” means the entity contracted with the Board to perform services required to administer the program or the entity’s designee.

3. Amend 16 CCR 1357.1

Purpose: The purpose of amending section 1357.1 is to delete outdated language relating to the Board’s defunct impaired physician diversion program and add new language relevant to the PHWP. In this section, the Board proposes to delete the word “applicant” and replace it with the word “participant,” as the PHWP uses the word “participant” throughout.

Anticipated Benefits: The Board anticipates that interested parties will benefit from the terms being updated to make them relevant to the PHWP.

Rationale: This proposed amendment is necessary to update this section to remove outdated language and add new language applicable to the PHWP. The PHWP uses the word “participant” rather than “applicant,” so the proposed change is necessary for clarity in the regulations.

Amend section 1357.1(a)

Purpose: The purpose of amending section 1357.1(a) is to delete the word “applicant,” and replace it with the word “participant,” which is used throughout the PHWP. This section will also be amended to clarify that the participant must be a California licensed physician and surgeon, which is the correct title for “physicians” in California, or hold a physician and surgeon postgraduate training license in this state. This section will also be amended to strike the phrase “be otherwise legally authorized to practice medicine,” since the other modifications to this section make this language unnecessary.

Anticipated Benefits: The Board anticipates that interested parties will benefit from the language being updated to reflect terms used in the PHWP and to remove outdated and extraneous language.

Rationale: These proposed amendments are necessary to update this section to remove outdated and extraneous language and add new language applicable to the PHWP. The PHWP uses the word “participant” rather than “applicant,” so the proposed change is necessary for clarity in the regulations. Additionally, the modifications to this section are necessary to specify that participants in the PHWP must be either California

licensed physicians and surgeons or hold a physician and surgeon postgraduate training license in this state.

Amend section 1357.1(b)

Purpose: The purpose of amending section 1357.1(b) is to delete the word “applicant,” and replace it with the word “participant.” This section will also be amended to strike the words “dangerous drugs” and replace it with the word “substances.” This section will further be amended to strike the text, “or suffer from mental or physical disability.” Additionally, this section will be amended to strike “physician’s” and replace it with “participant’s.” Finally, it will be amended to correct a typo by changing “safety” to “safely.”

Anticipated Benefits: The Board anticipates that interested parties will benefit from the language being updated to reflect terms used in the PHWP, clarify that the PHWP is for participants who are found to abuse substances or alcoholic beverages, and to correct a typographical error in the text.

Rationale: These proposed amendments are necessary to update the text with terms used in the PHWP, and will replace the word “applicant,” with “participant.” It will further replace “dangerous drugs” with “substances” to update the language to reflect the current term used in the PHWP. It is necessary to strike the phrase “or suffer from mental or physical disability,” because pursuant to BPC section 2340, the PHWP is established to aid licensees with substance abuse issues. Licensees who do not have substance abuse issues are not authorized for admission into the PHWP. Further, it is necessary to replace the word “physician’s” with “participant’s” to update the language with a defined term which clarifies who is eligible for admission into the PHWP. Finally, it is necessary to correct a typo by changing “safety” to “safely” to improve this section’s clarity and readability.

Amend section 1357.1(c)

Purpose: The purpose of amending section 1357.1(c) is to delete the word “applicant,” and replace it with the word “participant.” This section will also be amended to add “or have been referred by the Board pursuant to a disciplinary order.”

Anticipated Benefits: The Board anticipates that interested parties will benefit from the language being updated to reflect terms used in the PHWP, and to clarify that the participants may either self-refer into the program or be referred by the Board pursuant to a disciplinary order.

Rationale: These proposed amendments are necessary to update the text to make it applicable to the PHWP, and will replace the word “applicant,” with “participant.” It will further add the phrase, “or have been referred by the Board pursuant to a disciplinary

order.” This amendment with clarify that the two ways to participate in the PHWP is either through self-referral or referral by the Board as part of a disciplinary order. This is not a diversion program, so the Board will not refer a licensee to the PHWP outside of making it a requirement in a disciplinary order.

Amend section 1357.1(d)

Purpose: The purpose of amending section 1357.1(d) is to delete the word “applicant,” and replace it with the word “participant.” This section will also be amended to add the words “in writing” to indicate that the participant must agree “in writing” to undertake any medical or psychiatric examinations ordered by the PHWP.

Anticipated Benefits: The Board anticipates that interested parties will benefit from the language being updated to reflect terms used in the PHWP, and to clarify that the participants must agree “in writing” to undertake any medical or psychiatric examinations ordered by the PHWP.

Rationale: These proposed amendments are necessary to update the text to make it applicable to the PHWP, and will replace the word “applicant,” with “participant.” It will further add the words “in writing” to indicate that the participant must agree “in writing” to undertake any medical or psychiatric examinations ordered by the PHWP. This is necessary to provide clarity for the vendor and participants that this agreement to undertake any medical or psychiatric examinations ordered by the program must be in writing.

Amend section 1357.1(e)

Purpose: The purpose of amending section 1357.1(e) is to delete the word “applicant,” and replace it with the word “participant.”

Anticipated Benefits: The Board anticipates that interested parties will benefit from the language being updated to reflect terms used in the PHWP.

Rationale: These proposed amendments are necessary to update the text to make it applicable to the PHWP, and will replace the word “applicant,” with “participant,” which is a defined term in the PHWP regulations.

Add section 1357.1(f)

Purpose: The purpose of adding section 1357.1(f) is to require the participant to agree in writing to abstain from the use of alcohol and prohibited substances as defined in 16 CCR section 1361.51(e).

Anticipated Benefits: The Board anticipates that interested parties will benefit from this

language being added to require this written agreement to abstain from prohibited substances as part of participating in the PHWP. Participants will be required to agree in writing to abstain from use of alcohol and prohibited substances so that they will be aware of the expectations of the PHWP up front, since the program is required to notify the Board within one business day of receiving a positive test.

Rationale: This proposed addition is necessary to clarify the requirements for admission into the PHWP. Participants must agree in writing to abstain from use of alcohol and prohibited substances as defined in the Board's existing regulations implementing the Uniform Standards under 16 CCR section 1361.51(e). The requirement to abstain from use is necessary to protect the public and to further the rehabilitation of the participant.

Add section 1357.1(g)

Purpose: The purpose of adding section 1357.1(g) is to require the participant to agree in writing to comply with all practice restrictions imposed by the program.

Anticipated Benefits: The Board anticipates that interested parties will benefit from this language being added to require this written agreement for participants to comply with all practice restrictions imposed by the program as part of participating in the PHWP. Requiring this agreement in writing will alert participants that they may be subject to practice restrictions imposed by the program and must agree to comply with such restrictions for admission into the PHWP.

Rationale: This proposed addition is necessary to clarify the requirements for admission into the PHWP. Participants must agree in writing to comply with all practice restrictions imposed by the program. Accordingly, this will alert participants up front that they may be subject to practice restrictions imposed by the program and must agree in writing to comply. The requirement to comply with practice restrictions is necessary to protect the public and to further the rehabilitation of the participant.

Amend section 1357.1(h)

Purpose: The purpose of amending section 1357.1(h) is to delete the word "applicant," and replace it with the word "participant." This section will also be amended to delete the word "diversion" and to add the language to indicate that the participant must agree in writing to cooperate with all elements of the agreement "for admission into the program, including all sections of this article, and to pay all costs required for participation in the program."

Anticipated Benefits: The Board anticipates that interested parties will benefit from the language being updated to reflect terms used in the PHWP and clear language establishing that participants must agree in writing to cooperate with all elements of the admission agreement, including all sections of this article, and must agree to pay all

costs required for participation in the program.

Rationale: BPC section 2340.6(a) requires participants to enter into a written agreement with the program in which the participant agrees to pay all costs associated with their participation in the program. These proposed amendments are necessary to update this regulation on Criteria for Admission to make it applicable to the PHWP, and will replace the word “applicant,” with “participant,” which is a defined term in the PHWP regulations. It is necessary to strike the word “diversion,” since that term refers to the Board’s defunct diversion program. The PHWP is not a diversion program, so “diversion” must be deleted from the text. It is further necessary to add language to indicate that the participant must agree in writing to cooperate with all elements of the agreement “for admission into the program, including all sections of this article, and to pay all costs required for participation in the program,” to set forth the requirements for admission into the PHWP and improve clarity.

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

Purpose: The purpose of repealing 16 CCR sections 1357.2, 1357.3, 1357.4, 1357.5, 1357.6, and 1357.8 is to update the Board’s regulations by removing old sections that are no longer operational. The Board’s diversion program was discontinued as of July 1, 2008, and the authorizing statutes, BPC sections 2340 through 2356, were repealed as of January 1, 2009, by the terms of BPC section 2358 (repealed by its own terms).

Anticipated Benefit: Repealing outdated regulations pertaining to the Board’s former diversion program will improve the clarity of the Board’s regulations and reduce confusion as the Board is preparing to implement the PHWP.

Rationale: In 1980, the Legislature authorized the Board’s diversion program, which “diverted” substance abusing or otherwise impaired physicians out of the disciplinary process and into a program intended to monitor them during their recovery from addiction or other physical or mental illness. The Board discontinued the diversion program as of July 1, 2008, and the statutes authorizing the diversion program, former BPC sections 2340 through 2356, were repealed as of January 1, 2009, by the terms of BPC section 2358 (repealed by its own terms). The PHWP being proposed in this rulemaking has very different requirements from the former diversion program. Consequently, repealing 16 CCR sections 1357, 1357.1, 1357.2, 1357.3, 1357.4, 1357.5, 1357.6, and 1357.8, relating to the defunct diversion program is necessary to update the Board’s regulations and improve clarity.

5. Amend 16 CCR section 1357.9

Purpose: The purpose of amending section 1357.9 is to strike the term “Diversion” and make a non-substantive change to its title. Further, the proposal strikes “diversion” from the section and adds that the program shall keep the specified records in a paper or

electronic format that meets specified requirements for seven years from the date of creation or receipt by the program.

Anticipated Benefits: The Board anticipates that this amendment will benefit interested parties by updating this section to strike references to the defunct diversion program and by adding language to require the PHWP to maintain records in a usable, readable, and searchable format, which is necessary for auditing purposes and for extracting information required to be reported to the Board.

Rationale: This proposed amendment is necessary to update the regulation to strike references to the defunct diversion program and to add language to require the PHWP to maintain records in a paper or electronic format that is usable, readable, and searchable, which is necessary for auditing purposes and for extracting information required to be reported to the Board. 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 and regulations for the PHWP. For the audit to be effective and for the Board to be able to obtain the information it needs for its reports, this proposed amendment adds a records retention period of seven years, which was selected as a reasonable period to be useful for auditors for comparison purposes, and because it is consistent with the statute of limitations based on the date of an act or omission for most of the Board's cases pursuant to Business and Professions Code section 2230.5.

Amend 16 CCR section 1357.9(a)

Purpose: The purpose of amending section 1357.9(a) is to add "participant" to describe the intake reports and case analyses and update the internal lettering in the section.

Anticipated Benefit: The Board anticipates that this amendment will improve clarity and consistency by adding "participant" to describe the intake reports and case analyses and updating the internal lettering in the section.

Rationale: This proposed amendment is necessary to add "participant" to describe the intake reports and case analyses, which will distinguish these documents from other documents the program may have, and to update the internal lettering. These changes are necessary to improve clarity and consistency.

Amend 16 CCR section 1357.9(b)

Purpose: The purpose of amending section 1357.9(b) is to add the word "participant" to describe the agreements and amendments thereto that must be retained and update the internal lettering in the section.

Anticipated Benefit: The Board anticipates that this amendment will improve clarity and

consistency by adding “participant” to describe the agreements and amendments thereto that must be maintained and updating the internal lettering.

Rationale: This proposed amendment is necessary to add “participant” to describe the agreements and amendments thereto, which will distinguish these documents from other documents the program may have, and to update the internal lettering. These changes are necessary to improve clarity and consistency.

Amend 16 CCR section 1357.9(c)

Purpose: The purpose of amending section 1357.9(c) is to strike old language relating to the defunct diversion program, and to add “participant” to describe the file notes, laboratory and incident reports, and update the internal lettering in the section.

Anticipated Benefit: The Board anticipates that this amendment will improve clarity and consistency by striking old language applicable to the Board’s defunct diversion program and adding “participant” to describe the file notes, laboratory and incident reports, and updating the internal lettering.

Rationale: This proposed amendment is necessary to strike old language applicable to the Board’s defunct diversion program and to add “participant” to describe the file notes, laboratory and incident reports, which will distinguish these documents from other documents the program may have, and to update the internal lettering. These changes are necessary to improve clarity and consistency.

Amend 16 CCR section 1357.9(d)

Purpose: The purpose of amending section 1357.9(d) is to strike old language relating to the defunct diversion program, and to add language to require the program to retain all other records relating 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.

Anticipated Benefit: The Board anticipates that this amendment will improve clarity by striking old language applicable to the Board’s defunct diversion program and adding language that sets forth that all other records relating to the participant’s performance in the program must be retained by the program.

Rationale: This proposed amendment is necessary to strike old language applicable to the Board’s defunct diversion program and to add language that sets forth that all other records relating to the participant’s performance in the program must be retained by the program. These records must be maintained and available for data extraction for reports requested by the Board and for auditors to conduct a thorough review of the program.

Amend 16 CCR section 1357.9(e)

Purpose: The purpose of amending section 1357.9(e) is to reorder this subdivision and add language applicable to the PHWP. The old subdivision (e) is now subdivision (c), and new language is added to subdivision (e) to require the program to retain all correspondence with the Board.

Anticipated Benefit: The Board anticipates that this amendment will improve clarity by reordering the section and clarifying that the program is required to retain its correspondence with the Board.

Rationale: This proposed amendment is necessary to reorder the section, which was applicable to the Board's defunct diversion program. The old subdivision (e) is now subdivision (c). The new language under subdivision (e) requires the program to maintain all correspondence with the Board. These records must be maintained and available for auditors to conduct a thorough review of the program, which will verify that the program is submitting reports and notifications to the Board when required. Additionally, all correspondence with the Board must be retained so that data may be extracted when requested by the Board and produced when required.

Amend 16 CCR section 1357.9(f)

Purpose: The purpose of amending section 1357.9(f) is to strike old language applicable to the Board's defunct diversion program and to add language that requires the program to retain all correspondence with contractors.

Anticipated Benefit: The Board anticipates that this amendment will improve clarity by striking old language applicable to the Board's defunct diversion program and clarifying that the program is required to retain all correspondence with contractors.

Rationale: This proposed amendment is necessary to strike old language relating to the Board's defunct diversion program and to add language that requires the program to retain all correspondence with contractors. Correspondence with contractors, which by definition includes subcontractors, must be maintained and available for auditors to conduct a thorough review of the program, to ensure that the program is selecting contractors that meet the requirements of the law and that the program is providing appropriate oversight and guidance to contractors providing services to participants. Additionally, all correspondence with contractors must be retained so that data may be extracted when requested by the Board and produced when required.

6. Adopt 16 CCR section 1357.10

Adopt “Requirements for the Physician and Surgeon Health and Wellness Program Vendor and Participants” as Title for 16 CCR section 1357.10

Purpose: The purpose of adopting 16 CCR section 1357.10 is to set out requirements for program vendors and participants for the PHWP in a regulation section with a clear title.

Anticipated Benefits: The Board anticipates interested parties will benefit from clearly stated requirements for PHWP vendors and participants and having this information in a clearly labelled section that is easy to find in the PHWP regulations.

Rationale: This subsection is necessary to set out the requirements for PHWP vendors and participants and the title clearly indicates these matters are covered in this section. This section is based on BPC sections 2340.2, 2340.4, and 2340.6, which set out requirements for PHWP vendors and participants.

Adopt 16 CCR section 1357.10(a)

Purpose: The purpose of adopting proposed section 1357.10(a) is to alert interested parties that the vendor is required to comply with and is responsible for ensuring that all contractors and subcontractors comply with the Board’s requirements contained in Article 14 of the BPC and the related regulations.

Anticipated Benefit: The Board anticipates that section 1357.10(a) will provide clarity to interested parties on the vendor requirements to ensure that the vendor, contractors, and subcontractors comply the requirements set forth in Article 14 of the BPC, as well as the related regulations.

Rationale: Proposed section 1357.10(a) is necessary to make clear that the vendor is required to comply with Article 14 of the BPC and related regulations and that they are required to select and monitor contractors and subcontractors appropriately to ensure their compliance with the law, as well. Setting forth these expectations enhances the effectiveness of the PHWP and furthers the mission of consumer protection, as well as the goal of rehabilitating licensees with substance abuse issues.

Adopt 16 CCR section 1357.10(b)

Purpose: The purpose of adopting proposed section 1357.10(b) is to make it clear to participants and the vendor that participants must meet the criteria for admission outlined in 16 CCR section 1357.1.

Anticipated Benefit: The Board anticipates that section 1357.10(b) will provide clarity to interested parties on the vendor and participant requirements that licensees must meet the criteria set forth in section 1357.1 to participate in the program.

Rationale: Proposed section 1357.10(b) is necessary for consistency within the PHWP regulations and to make clear to interested parties that licensees must meet the criteria set forth in section 1357.1 for admission into the program.

Adopt 16 CCR section 1357.10(c)

Purpose: The purpose of proposed section 1357.10(c) is to make it clear that if a participant is ordered to undergo a clinical diagnostic evaluation, the evaluation must meet the requirements already approved through the Board's regulations implementing the Uniform Standards for clinical diagnostic evaluations under 16 CCR section 1361.5(c)(1)(A)-(D). The purpose of this section is to also indicate that that references to the "Board" in section 1361.5(c)(1)(A)-(D) shall mean the Board and the vendor for Board-referred participants, and only the vendor for self-referred participants. Moreover, 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 shall mean the terms of the participant's monitoring agreement with the vendor for self-referred participants.

Anticipated Benefits: The Board anticipates that this proposal will provide clarity for the interested parties on the requirements for a clinical diagnostic evaluation for a PHWP participant. This proposal refers the interested parties to the requirements under existing regulation, 16 CCR section 1361.5(c)(1)(A)-(D), which implemented Uniform Standard #1 and has already been approved for clinical diagnostic evaluations. It also ensures the confidentiality of individuals who self-refer into the program and clarifies terms for self-referred participants.

Rationale: 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. To meet the statutory mandate for complying with the Uniform Standards, this proposed section refers interested parties to existing regulation, 16 CCR section 1361.5(c)(1)(A)-(D), which sets forth the requirements for clinical diagnostic evaluations for substance abusing licensees.

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, only the vendor will be in communication with the

contractor providing the clinical diagnostic evaluation for a self-referred participant. In contrast, for individuals who are referred to the PHWP by the Board pursuant to their terms and conditions of probation, this proposed regulation provides that references to the “Board” in 16 CCR section 1361.5(c)(1)(A)-(D) shall mean the Board and the vendor.

Finally, to further distinguish between Board-referred and self-referred participants, this proposed section is necessary to clarify that 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 shall mean the terms of the participant’s monitoring agreement with the vendor for self-referred participants.

Adopt 16 CCR section 1357.10(d)

Purpose: The purpose of proposed section 1357.10(d) is to require that if the participant has an employer, all the notification and consent requirements set forth in existing regulation, 16 CCR section 1361.5(c)(2), shall apply.

Anticipated Benefits: The Board anticipates that proposed section 1357.10(d) will provide clarity for interested parties on the requirements for the participant to comply with the notification and consent requirements currently set forth under 16 CCR section 1361.5(c)(2). Open channels of communication will help keep the participant on track with rehabilitation goals and will give the vendor the ability to quickly intervene to protect patients if the participant is non-compliant with the program requirements.

Rationale: BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standard #3 sets forth the requirements for licensee notification of employer information and consent for communication. The Board’s regulations implementing the Uniform Standards became effective in July 2015. To meet the statutory mandate for the PHWP to comply with the Uniform Standards, this proposed section refers interested parties to existing regulation, 16 CCR section 1361.5(c)(2), which sets forth the requirements for licensees subject to this section to provide the Board with notice of their employer information and consent for the Board, the worksite monitor, and the licensee’s employers and supervisors to communicate regarding the licensee’s work status, performance, and monitoring.

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 with the program, this proposed section ensures their confidentiality by clarifying that references to the “Board” in section 1361.5(c)(2) 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. In contrast, for individuals who are

referred to the PHWP pursuant to their terms and conditions of probation, this proposed regulation provides that references to the “Board” in 16 CCR section 1361.5(c)(2) shall mean the Board and the vendor.

Adopt 16 CCR section 1357.10(e)

Purpose: The purpose of proposed section 1357.10(e) is to set forth the requirements for biological fluid testing. This section indicates under section 1357.10(e)(1) that participants are required to abstain from the use, consumption, ingestion, or administration of prohibited substances as defined under existing regulation, 16 CCR section 1361.51(e). Further, section 1357.10(e)(2) requires participants to undergo random biological fluid testing consistent with the provisions set forth in existing regulation, 16 CCR section 1361.5(c)(3). This proposed section also provides for the confidential participation by participants who do not have a practice restriction based on substance abuse issues. Finally, the purpose of section 1357.10(e)(2)(A) is to carve out an exception to the applicability of 16 CCR section 1361.5(c)(3)(l)(4) for a participant who self-referred to the PHWP to prohibit tolling of the biological fluid testing requirements, even if practicing out of state, so long as they have a license to practice in California.

Anticipated Benefits: The Board anticipates that proposed section 1357.10(e) will provide clarity for interested parties regarding the requirements for the participant to abstain from the use of prohibited substances and requirements for biological fluid testing. Participants will be required to comply with the biological fluid testing schedule set forth in existing regulation, 16 CCR section 1361.5(c)(3). This testing frequency schedule allows for appropriate randomness in testing, without regular interval or pattern, and promotes consumer protection and rehabilitation of the licensee. This proposed section also ensures that a self-referred participant who still holds a license to practice medicine in California will participate in biological fluid testing even if practicing out of state. This furthers consumer protection and licensee rehabilitation by requiring self-referred participants to complete the PHWP biological fluid testing requirements, and ensuring they are not practicing medicine while under the influence of drugs or alcohol.

Rationale: BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standard #4 sets forth the requirements for biological fluid testing for prohibited substances. The Board’s regulations implementing the Uniform Standards became effective in July 2015. To meet the statutory mandate for the PHWP to comply with the Uniform Standards, this proposed section refers interested parties to existing regulation, 16 CCR section 1361.5(c)(3), which sets forth the requirements for biological fluid testing as mandated by the Uniform Standards. Additionally, this proposed language refers to existing regulation, 16 CCR section 1361.51(e) to define “prohibited substances” to ensure the Board’s regulations applicable to substance abusing licensees are aligned.

The biological fluid testing schedule set forth in existing regulation, 16 CCR section 1361.5(c)(3), prevents participants from gauging when they will be tested. Further, by establishing minimum testing frequency “ranges” and employing randomness in testing, participants will not be able to consider one or more days as a “safety period” following the submission of a biological sample for testing. Requiring a participant to submit a specimen on the same day as directed eliminates the ability for a participant to “flush” their system overnight.

Moreover, by referencing existing regulation, 16 CCR section 1361.5(c)(3), this proposed section will provide certain exceptions to the testing frequency schedule and permit flexibility to allow the vendor to evaluate each participant’s situation on a case-by-case basis and impose testing requirements within an approved range. Additionally, by referencing existing regulation, 16 CCR section 1361.5(c)(3), this proposed section will allow the vendor to require a participant to undergo testing on any day, including weekends and holidays, and allow the vendor to increase the number of tests for any reason.

Furthermore, 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 references to the “Board” in 16 CCR section 1361.5(c)(3) shall mean the vendor. Thus, a self-referred participant will only communicate with the vendor and the vendor’s contractors regarding biological fluid testing, and not the Board. In contrast, for individuals who are referred to the PHWP pursuant to their terms and conditions of probation, this proposed regulation provides that references to the “Board” in 16 CCR section 1361.5(c)(3) shall mean the Board and the vendor.

The proposed language under section 1357.10(e)(2)(A) is necessary to preclude tolling of biological fluid testing for a self-referred participant to avoid the licensee from being able to end monitoring by moving out of state. This tolling prohibition prevents a substance abusing licensee from practicing unmonitored in another state, and also from returning to California to practice medicine without having been subjected to rigorous biological fluid testing. Board-referred participants do not pose this same risk, since their disciplinary action and terms and conditions of probation are public on the Board’s website and since they are reported to the National Practitioner Data Bank to alert other states where they have or may seek a license. In contrast, self-referred participants are unknown to the Board, and consumer protection requires them to complete the PHWP, even if they move out of state, or be reported to the Board for investigation and potential disciplinary action to protect the public and further the licensee’s rehabilitation.

Adopt 16 CCR section 1357.10(f)

Purpose: The purpose of proposed section 1357.10(f) is to require the vendor to notify the Board in writing within one business day of receiving biological fluid test results indicating that a participant has tested positive for a prohibited substance.

Anticipated Benefits: The Board anticipates that this proposed section will further consumer protection by requiring the vendor to report a positive biological fluid test to the Board within one business day of receiving the results, which will trigger an investigation and enforcement action as appropriate. In addition to furthering public protection, this provision will support the licensee's rehabilitation by encouraging compliance with the PHWP.

Rationale: BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standard #13 sets forth the requirements for a vendor to report any major violation to the Board within one business day. A positive biological fluid test is a major violation pursuant to Uniform Standard #10. This proposed section is necessary to set forth the requirement for a vendor to report a positive biological fluid test in writing to the Board within one day of receiving the results. Participants are required to abstain from the use of prohibited substances as defined in section 1361.51(e). A positive biological fluid test result would be a major violation of the PHWP and must be reported expeditiously within one business day to protect the public.

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. This proposed section does not distinguish between a self-referred participant and a Board-referred participant, however, since a positive biological fluid is a major violation and must be reported to the Board.

Adopt section 1357.10(g)

Purpose: The purpose of section 1357.10(g) is to set forth the requirements for laboratories/testing locations, and specimen collectors contracting with the vendor regarding biological fluid testing for PHWP participants. These contractors that provide testing locations, laboratory services, or specimen collection will have to comply with the provisions set forth in existing regulation, 16 CCR section 1361.54. This proposed section also provides for the confidential participation by a licensee who does not have a practice restriction based on substance abuse issues.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties, by requiring the vendor to contract with laboratories/testing locations, and specimen collectors that meet the Uniform Standards as required under BPC section 2340.2(e). Complying with these requirements will ensure that the contractors

meet required standards for providing legally reliable, timely testing results.

Rationale: BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standards #4, #8, and #13(2)(a), set forth requirements for biological fluid testing, laboratories/testing locations, and specimen collectors, and the timeframes for reporting non-negative and positive test results. The Board's regulations implementing the Uniform Standards became effective on July 1, 2015. Consequently, to meet the statutory mandate for complying with the Uniform Standards, this proposed section refers interested parties to existing regulation, 16 CCR section 1361.54, which sets forth the requirements for laboratories/testing locations, and specimen collectors.

Existing regulation, 16 CCR section 1361.54, requires laboratories/testing locations, and specimen collectors to among other requirements, meet specified national standards, have appropriate testing and laboratory facilities, have testing locations throughout California, have a phone or computer system that permits daily check-ins for testing, be able to process and report non-negative test results within one business day and provide legally defensible results with seven business days.

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 references to the "Board" in existing regulation, 16 CCR section 1361.54, shall mean the vendor. Thus, only the vendor will be in communication with the contractors providing laboratory/testing location and specimen collection services for a self-referred participant. In contrast, for individuals who are referred to the PHWP by the Board pursuant to their terms and conditions of probation, this proposed regulation provides that references to the "Board" in 16 CCR section 1361.54 shall mean the Board and the vendor.

This proposed section is necessary for consumer protection and licensee rehabilitation because it requires the vendor to contract with laboratories/testing locations and specimen collectors that meet the requirements of the Uniform Standards and the Board's existing regulations. This promotes the reliability of the biological fluid test results so that the vendor and the Board know when it is appropriate to restrict a participant's practice and take further action.

Adopt 16 CCR section 1357.10(h)

Purpose: The purpose of proposed section 1357.10(h)(1)-(9) is to provide the criteria the vendor and its contractors shall consider when determining whether inpatient, outpatient, or other type of treatment is necessary for a participant.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties by requiring the vendor and its contractors to consider each participant's individual circumstances and history when determining appropriate treatment, consistent with the Uniform Standards.

Rationale: BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standard #6 sets forth the factors that must be considered when determining whether inpatient, outpatient, or other type of treatment is necessary. This proposed section is compliant with Uniform Standard #6, as it lays out all of the required factors to be considered, including, the recommendation of the clinical diagnostic evaluation; license type; participant's history; documented length of sobriety; treatment history; medical history; nature, duration and severity of substance abuse; and whether the participant is a threat to themselves or the public. This proposed section is necessary for consumer protection and participant rehabilitation because it requires the consideration of the factors set forth in the Uniform Standards relevant to making treatment decisions for substance abusing licensees.

Adopt 16 CCR section 1357.10(i)

Purpose: The purpose of proposed section 1357.10(i)(1)-(6) is to set forth the requirements treatment providers must meet to be able to contract with the vendor to provide services to PHWP participants. Additionally, this section provides a distinction between Board-referred participants and self-referred participants, ensuring that treatment and progress reports for self-referred participants only go to the vendor and not to the Board.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties by requiring the vendor to contract with qualified licensed and/or accredited contractors, consistent with the Uniform Standards. The Board anticipates that requiring the vendor to use qualified contractors will promote integrity and confidence in the PHWP, and will further consumer protection and rehabilitation of the participants.

Rationale: BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standard #13(2)(d) sets forth the requirements for treatment providers contracting with a vendor to provide services to a participant. This proposed section is compliant with Uniform Standard #13.2(d).

Proposed section 1357.10(i)(1)-(6) requires the vendor to contract with treatment providers who meet the requirements set forth in Uniform Standard #13(2)(d). The requirements set forth in this section mirror the requirements under Uniform Standard #13(2)(d) and are necessary to ensure the vendor contracts with credentialed, experienced treatment providers, with appropriate resources.

Additionally, the Board has added the specific requirement under proposed sections 1357.10(i)(2) and (4) that the vendor use contractors with a minimum of three years' experience in treating health professionals with substance abuse problems. Three years' experience was determined to be the appropriate minimum level of experience required for a treatment provider providing services under the PHWP, because the vendor's medical director will be providing oversight. Substance abusing physicians are a unique population that can pose a serious risk of harm to patients and require careful, experienced treatment and monitoring. Less than three years' experience was determined to not provide sufficient breadth of knowledge to promote confidence that providers contracting with the PHWP will effectively protect the public while monitoring and supporting participants in recovery.

Further, 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, proposed section 1357.10(i)(6) ensures their confidentiality by clarifying that treatment and progress documentation shall go to the vendor for self-referred participants, and not to the Board.

Adopt 16 CCR section 1357.10(j)

Purpose: The purpose of proposed section 1357.10(j) 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.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties by requiring support group meetings to comply with existing regulation, 16 CCR section 1361.5(c)(4). Requiring support group meetings to meet these requirements is consistent with the Uniform Standards and will benefit the participants in their recovery, and thus promote consumer protection.

Rationale: BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standards #5 and #13(2)(b) set forth requirements for support group meetings. The Board's regulations implementing the Uniform Standards became effective on July 1, 2015. This proposed section refers interested parties to existing regulation, 16 CCR section 1361.5(c)(4), which sets forth the requirements for support group meetings, consistent with the Uniform Standards.

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. Further, existing regulation, 16 CCR section 1361.5(c)(4), requires support group facilitators to provide

reports to the Board to show the participant's dates and locations of meetings attended and the participant's level of participation and progress. Additionally, the facilitator is required to report a participant's unexcused absence to the Board within 24 hours. These reports permit the Board to review the participant's progress and to take appropriate action if the participant is not in compliance with the terms and conditions of their probation.

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 references to the "Board" in section 1361.5(c)(4) shall mean the vendor. Thus, only the vendor will be in communication with the contractors providing support group meetings for a self-referred participant. In contrast, for individuals who are referred to the PHWP by the Board pursuant to their terms and conditions of probation, this proposed regulation provides that references to the "Board" in section 1361.5(c)(4) shall mean the Board and the vendor.

This proposed section is necessary for consumer protection and licensee rehabilitation because it requires the vendor to contract with support group contractors that meet the requirements of the Uniform Standards and the Board's existing regulations. This promotes the use of qualified support group facilitators and open communication about the participant's progress and compliance so appropriate action can be taken to support the participant's recovery and protect the public.

Adopt 16 CCR section 1357.10(k)

Purpose: The purpose of proposed section 1357.10(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. This proposed section also provides for the confidential participation by a licensee who does not have a practice restriction based on substance abuse issues.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties by requiring worksite monitors to comply with existing regulation, 16 CCR section 1361.5(c)(5). The Board anticipates that requiring worksite monitors to meet these required standards will benefit the participants in the PHWP in their recovery, and thus promote consumer protection.

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. The Board's regulations implementing the Uniform Standards became effective on July 1, 2015. Consequently, to meet the statutory mandate for complying with the Uniform Standards, this proposed section refers interested parties to existing

regulation, 16 CCR section 1361.5(c)(5), which sets forth the 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. The worksite monitor is required to report any suspected substance abuse within the required time periods and must submit monthly reports containing specified information.

Further, under existing regulation, 16 CCR section 1361.5(c)(5), if the worksite monitor resigns or is no longer available, the participant shall, within five days, submit for prior approval the name of person(s) qualified and willing to assume the responsibility. If the participant fails to comply with this requirement, the Board shall issue a cease practice order, which shall remain in place until the participant is notified in writing that he or she may return to the practice of medicine.

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 references to the "Board" in section 1361.5(c)(5) shall mean the vendor. Thus, only the vendor will be in communication with the practice monitors for a self-referred participant. In contrast, for individuals who are referred to the PHWP by the Board pursuant to their terms and conditions of probation, this proposed regulation provides that references to the "Board" in section 1361.5(c)(4) shall mean the Board and the vendor.

This proposed section is necessary for consumer protection and licensee rehabilitation because it requires worksite monitors approved by the vendor to meet the requirements of the Uniform Standards and the Board's existing regulations. This promotes the use of qualified worksite monitors and open communication about the participant's progress and compliance so appropriate action can be taken to support the participant's recovery and protect the public.

Adopt 16 CCR section 1357.10(I)

Purpose: The purpose of proposed section 1357.10(I) 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.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties by ensuring that participants must meet the criteria set forth under existing regulation, 16 CCR section 1361.53 before being permitted to return to full or part-time practice. Under this proposed section, participants who demonstrate stability in their sobriety and compliance with the PHWP may have their practice restrictions lifted. This proposal furthers consumer protection and supports participants in their rehabilitation efforts by lifting practice restrictions only once they meet the required criteria.

Rationale: BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standard #11 sets forth the criteria to be evaluated prior to returning a licensee to full-time practice. The Board's regulations implementing the Uniform Standards became effective on July 1, 2015. Consequently, to meet the statutory mandate for complying with the Uniform Standards, this proposed section refers interested parties to existing regulation, 16 CCR section 1361.53. This existing regulation is consistent with Uniform Standard #11, and sets forth the criteria to be considered before authorizing a licensee to return to practice after the issuance of a cease-practice order or imposition of practice restrictions, including demonstrated, sustained compliance with the current recovery program; demonstrated ability to practice medicine safely; and six months of negative biological fluid testing, two positive worksite monitor reports (if currently being monitored), and complete compliance with terms and conditions of probation.

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 references to the "Board" in section 1361.53 shall mean the vendor. Thus, only the vendor will be in communication with the contractors for a self-referred participant. In contrast, for individuals who are referred to the PHWP by the Board pursuant to their terms and conditions of probation, this proposed regulation provides that references to the "Board" in section 1361.53 shall mean the Board and the vendor. Moreover, it clarifies that references to "probation" refer to probation ordered by the Board for Board-referred participants and shall mean the terms of the participant's monitoring agreement for self-referred participants.

This proposed section is necessary for consumer protection and licensee rehabilitation to ensure that a participant's practice restrictions are not lifted without consideration of the criteria required by Uniform Standard #11 and existing regulation, 16 CCR section 1361.53.

7. 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.

Anticipated Benefits: The Board anticipates interested parties will benefit from clearly stated reporting requirements for program vendors and notice to participants regarding public disclosure of practice restrictions and having this information in a clearly labelled section that is easy to find the PHWP regulations.

Rationale: This subsection is necessary to set out the reporting requirements for PHWP vendors and give participants notice regarding public disclosure of practice restrictions and the title clearly indicates these matters are covered in this section. This section is based on BPC sections 2340.2, 2340.4, and 2340.6, which set out requirements for PHWP vendors and participants.

Adopt 16 CCR section 1357.11

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

Finally, this proposal requires the Board to remove the practice restriction from the participant's profile within one business day of written notification from the vendor that the practice restriction has been lifted. This provision is necessary to ensure the participant's profile timely and accurately reflects their practice status and supports both the rehabilitation process and public protection.

8. Adopt 16 CCR section 1357.12

Adopt "Reports of Participant Violations, Withdrawals, and Terminations to the Board; Inquiries by the Board" as Title for 16 CCR section 1357.12

Purpose: The purpose of adopting 16 CCR section 1357.12 is to set out reporting requirements for program vendors regarding participant violations, withdrawals or terminations, and the time in which a vendor must respond to Board inquiries all in a regulation section with a clear title.

Anticipated Benefits: The Board anticipates interested parties will benefit from clearly stated reporting requirements for program vendors regarding participant violations, withdrawals or terminations, and the clear establishment of the time in which a vendor must respond to Board inquiries and having this information in a clearly labelled section that is easy to find in the PHWP regulations.

Rationale: This subsection is necessary to set out the reporting requirements for program vendors on participant violations, withdrawals or terminations, and establishes the time in which a vendor must respond to Board inquiries and the title clearly indicates these matters are covered in this section. This section is based on BPC sections 2340.2, 2340.4, and 2340.6, which set out requirements for PHWP vendors and participants.

Adopt 16 CCR section 1357.12(a)

Purpose: The purpose of proposed section 1357.12(a) is to require the vendor to report participants' major violations, as defined in existing regulation 16 CCR section 1361.52(a), in writing to the Board within one business day of finding that the participant committed a major 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 major violation of the program requirements. Timely notification of a major 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.

Rationale: BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. This proposed section complies with Uniform Standard #13(1). Proposed section 1357.12(a) requires the vendor to notify the Board in writing within one business day of finding a participant committed a major violation as defined in existing regulation, 16 CCR section 1316.52(a). Further, the vendor must identify the name and license number of the participant and provide a detailed description of the violation(s). This proposal is necessary to comply with the Uniform Standards, and to alert the Board quickly when a major violation occurs, so that the Board may investigate and take appropriate action necessary for consumer protection.

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.

Rationale: BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. This proposed section complies with Uniform Standard #13(1). Proposed section 1357.12(b) requires the vendor to notify the Board in writing within five business days of finding that a participant committed a minor violation as defined in existing regulation 16 CCR section 1316.52(c). Further, the vendor must identify the name and license number of the participant and provide detailed description of the violation(s). This proposal is necessary to comply with the Uniform Standards, and to alert the Board within the required timeframe when a minor violation occurs, so that the Board may investigate and take appropriate action necessary for consumer protection.

Adopt 16 CCR section 1357.12(c)

Purpose: The purpose of proposed section 1357.12(c) is to require the vendor to report in writing to the Board each participant who withdraws or is terminated from the PHWP within one business day of the withdrawal or termination, and to identify the participant's name, license number, the date of enrollment in the program, the date of withdrawal or termination from the program, and a description of the circumstances leading up to the withdrawal or termination.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties by ensuring the Board is notified within one business day about a participant's withdrawal or termination from the program. Notifying the Board about withdrawals and terminations within one business day is necessary for consumer protection and will allow the Board to investigate the matter and take enforcement action as warranted. Such reporting requirements also serve as an incentive to participants to comply with the program requirements.

Rationale: BPC section 2340.4(f) requires the vendor to have a system for immediately reporting a participant who withdraws or is terminated from the program to the Board. Accordingly, proposed section 1357.12(c) requires the vendor to notify the Board in writing within one business day if a participant withdraws or is terminated from the program. Requiring a written report within one business day of a participant's withdrawal or termination from the program is necessary for consumer protection, as a participant's withdrawal or termination may indicate that they are not safe to practice and require expedient review by the Board for possible enforcement action.

Adopt 16 CCR section 1357.12(d)

Purpose: The purpose of proposed section 1357.12(d) is to require the vendor to provide a written response to the Board indicating whether the licensee is a participant in the PHWP within three business days of a Board inquiry made after the Board initiates an investigation on the licensee.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties by providing the Board with timely information about whether the licensee is in the PHWP and will serve as a crosscheck on the participant's compliance with the PHWP and the program's compliance with monitoring and reporting.

Rationale: BPC section 2340.2(d) requires the PHWP to respond to a Board inquiry as to whether a licensee with an open investigation is enrolled in the program. Proposed section 1357.12(d) is necessary to make the statute more specific by requiring the vendor to respond to the Board's inquiry as to whether the licensee is a participant in the program within three business days. A response within three business days was determined to be a timely written response for this requirement, as the information is

being sought following the Board having opened an investigation into the licensee for potential violation of the Medical Practice Act to assist in evaluating potential risk to patients and appropriate enforcement action.

9. Adopt 16 CCR section 1357.13

Adopt “Vendor Communication with the Board; Annual Reports” as Title for 16 CCR section 1357.13

Purpose: The purpose of adopting 16 CCR section 1357.13 is to set out reporting requirements for program vendors responding to a written request by the Board and a requirement that vendors report yearly, by or before August 31, specified information to the Board for inclusion in the Board’s annual report all in a regulation section with a clear title.

Anticipated Benefits: The Board anticipates interested parties will benefit from this section setting out reporting requirements for program vendors responding to a written request by the Board, and a requirement that vendors report yearly, by or before August 31, specified information to the Board for inclusion in the Board’s annual report and having this information in a clearly labelled section that is easy to find in the PHWP regulations.

Rationale: This section is necessary to set out the reporting requirements for program vendors responding to a written request by the Board and the requirement that vendors report yearly, by or before August 31, specified information to the Board for inclusion in the Board’s annual report and the title clearly indicates these matters are covered in this section. This section is based on BPC sections 2340.2, 2340.4, and 2340.6, which set out requirements for PHWP vendors.

Adopt 16 CCR section 1357.13(a)

Purpose: The purpose of proposed section 1357.13(a)(1)-(14), is to require the vendor to provide a written report containing de-identified information to the Board within 30 days of receiving a written request by the Board on the specified data elements, such as, among other things, the number of participants currently enrolled in the program, the number of participants who successfully completed their agreement period, the number of participants who were terminated from the program, and any other program statistics requested in writing by the Board regarding compliance with this article.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties by providing regular updates on measurable criteria and will allow the Board and the public to evaluate the effectiveness of the services and monitoring provided by the PHWP.

Rationale: 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. Additionally, BPC section 2340.4(g)(1) requires the vendor to provide regular communication to the Board, and to provide various specified program statistics.

Consequently, proposed sections 1357.13(a)(1)-(14) are necessary to comply with Uniform Standard #16 and to implement BPC section 2340.4(g)(1) and make it more specific by requiring the vendor to provide a written report containing de-identified information within 30 days of receiving a written request by the Board to clarify when the vendor must provide reports.

Proposed section 1357.13(a)(1) asks for the number of participants currently in the PHWP, because this information is required by BPC section 2340.4(g)(1).

Proposed sections 1357.13(a)(2) and 1357.13(a)(3) ask for the number of participants who self-referred into the PHWP and the number of participants referred by the Board as a condition of probation, respectively, because this information is required, in a slightly different manner, by BPC section 2340.4(g)(1) and by Uniform Standard #16. Breaking down these two categories separately is necessary to serve as a crosscheck to the number of participants reported under proposed section 1357.13(a)(1), and will provide the Board and stakeholders information on how the PHWP is being used.

Proposed section 1357.13(a)(4) asks for the number of participants who have successfully completed their agreement period, because this information is required by BPC section 2340.4(g)(1).

Proposed section 1357.13(a)(5) asks for the number of participants who successfully returned to practice, because this information is required by Uniform Standard #16.

Proposed sections 1357.13(a)(6) and 1357.13(a)(7) ask for the number of participants who withdrew from the PHWP and number of participants who were terminated, respectively, consistent with the BPC section 2340.4(g)(1) requirement to provide information as to participants who were terminated. Breaking down the categories of participants who were terminated and participants who withdrew separately will serve to crosscheck the reports provided to the Board pursuant to proposed section 1357.13(c). Additionally, proposed sections 1357.13(a)(6) and 1357.13(a)(7) ask for the reasons for withdrawal and termination, which is necessary so the Board may obtain information on trends that can be used to improve the PHWP.

Proposed section 1357.13(a)(8) asks for the number of participants who committed major violations, as defined in section 1361.52(a), or minor violations as defined in section 1361.52(c), and the types of violations committed, consistent with Uniform Standard #16 and the general requirements of BPC section 2340.4(g)(1). This

information is necessary to crosscheck the reports provided to the Board for major and minor violations, and to obtain information on trends that can be used to improve the PHWP.

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. This section defines “patient harm” to mean injury or death to patient caused by the participant’s violation of the Medical Practice Act or regulations established through an admission or Board decision or order following an accusation. This definition is necessary to provide clarity around how patient harm will be determined for reporting purposes.

Proposed section 1357.13(a)(10) asks for the number and types of reports filed with the Board pursuant to proposed section 1357.12. This information is consistent with general requirements of BPC section 2340.4(g)(1) and is necessary to crosscheck the reports provided to the Board for major and minor violations, withdrawals, and terminations.

Proposed section 1357.13(a)(11) asks for a list of contractors performing treatment or other services, a description of their services, and the number of participants assigned to each, consistent with the general requirements of BPC section 2340.4(g)(1) for the program to provide program statistics. This section is necessary for the Board to evaluate trends and the effectiveness of the PHWP, treatment providers, and treatment modalities.

Proposed section 1357.13(a)(12) asks for the number of participants whose families received services through the program as required by BPC section 2340.4(d), the types of services received, and how many times services were provided. This section is necessary for the Board to evaluate the PHWP’s compliance with BPC section 2340.4(d), and the program’s effectiveness in reaching the participants’ families.

Proposed section 1357.13(a)(13) asks for the number and types of educational events provided by the vendor, the dates provided, the number and types of attendees, and the results of the evaluations of the events. This section is necessary for the Board to evaluate the PHWP’s compliance with BPC section 2340.2(a), which requires the PHWP to provide for the education of all licensed physicians and surgeons regarding the recognition and prevention of physical, emotional, and psychological problems.

Proposed section 1357.13(a)(14) asks for any other program statistics as 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 the BPC in Article 14. This proposed section is consistent with BPC section 2340.4(g)(1) and is necessary for the Board to obtain information to evaluate trends and the effectiveness of the PHWP.

Adopt 16 CCR section 1357.13(b)

Purpose: The purpose of proposed section 1357.13(b) is to require the reports under sections 1357.13(a)(1) through (a)(12) to include the specific types of substance abuse problems for which treatment was being sought (e.g., cocaine, alcohol, Demerol, etc.).

Anticipated Benefits: The Board anticipates that this information will be beneficial to interested parties to help identify trends and factors that impact the likelihood of successful rehabilitation and consumer protection.

Rationale: 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 and requires the statistical information to be broken down by substance abuse problem. Additionally, BPC section 2340.4(g)(1) requires the vendor to provide regular communication to the Board, and to provide various program statistics. Consequently, this proposal is necessary to comply with Uniform Standard #16 and will also assist the Board in identifying trends which could improve the PHWP's effectiveness and consumer protection.

Adopt 16 CCR section 1357.13(c)

Purpose: The purpose of proposed section 1357.13(c) is to require the vendor to provide the information required under subdivisions (a) and (b) on a yearly basis on or before August 31, for inclusion in the Board's annual report, which is published and provided to DCA and the Legislature.

Anticipated Benefits: The Board anticipates that this information will be beneficial to interested parties to help identify trends and factors that impact the likelihood of successful rehabilitation and help increase consumer protection.

Rationale: 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 and requires the Board to report specific information to DCA and the Legislature on a yearly basis. BPC section 2340.4(g)(1) requires the vendor to provide regular communication to the Board, and to provide various program statistics, including annual reports. The Board publishes its annual report in October of each year, thus this proposal requires the vendor to submit an annual report to the Board on or before August 31 for inclusion in the Board's annual report. This requirement is necessary for compliance with Uniform Standard #16 and implements and makes specific BPC section 2340.4(g)(1).

10. Adopt 16 CCR section 1357.14

Adopt “External Independent Audits; Responses to Findings, Grounds for Termination; Transfer of Care” as Title for 16 CCR section 1357.14

Purpose: The purpose of adopting 16 CCR section 1357.14 is to set out requirements regarding audits, a vendor’s response to audit findings, grounds for terminating a vendor, and a transfer of care plan all in a regulation section with a clear title.

Anticipated Benefits: The Board anticipates interested parties will benefit from this section setting out requirements regarding audits, a vendor’s response to audit findings, grounds for terminating a vendor, and a transfer of care plan and having this information in a clearly labelled section that is easy to find in the PHWP regulations.

Rationale: This section is necessary to set out the requirements for an external independent audit, a vendor’s response to audit findings, grounds for terminating a vendor, and the transfer of care plan, and the title clearly indicates these matters are covered in this section. This section is based on BPC sections 2340.2, 2340.4, 2340.6, and 2340.8, which set out requirements for PHWP vendors.

Adopt 16 CCR section 1357.14(a)

Purpose: The purpose of proposed section 1357.14(a) is to set forth the requirements for regular independent audits of the program which occur at least every three years, or as requested by the Board, by a qualified, independent reviewer approved by the Board. This proposed section also requires the cost of the audit to be borne by the vendor and to be factored into each participant’s fee.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties by ensuring the PHWP is audited 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.

Rationale: 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 and regulations for the PHWP. BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standard #15 sets forth the requirements for auditing vendors providing monitoring services for substance abusing licensees and requires the vendor to be audited at least every three years by a qualified reviewer or review team.

Proposed section 1357.14(a) requires the vendor to undergo an external, independent audit at least once every three years, or at any other time requested by the Board with at least 90 days’ notice, by individuals who are competent in conducting audits of

monitoring programs. The requirement that the program submit to an audit with 90 days' notice from the Board is necessary to clarify when an audit may occur outside of the three-year audit cycle and to provide the program with reasonable notice that an audit is forthcoming. Requiring compliance with an audit with at least 90 days' notice is a necessary tool for the Board to be able to respond to concerns about the program's safety and compliance with applicable statutes and regulations by requiring an independent review.

This section also sets forth the qualifications for the auditor to ensure they are competent and do not have a conflict of interest. The Board determined that the reviewer or review team must either be licensed certified public accountant(s) or public accountant(s) who have at least five years' experience in the professional practice of internal auditing and assessment processes and who are qualified to perform audits of monitoring programs. These qualifications were deemed necessary by the Board to ensure the reviewer or review team has the breadth of experience and qualifications necessary to generate a reliable report. Additionally, the reviewer must be from outside of the DCA and the Board and may not be under the control of the Board to ensure there is not a real or perceived conflict of interest.

Additionally, this section requires the vendor to bear the cost of the audit, and states that the cost shall be factored into each participant's fee. This provision is necessary to comply with BPC section 2340.8(b), which provides, in pertinent part, "The fee amount adopted by the board shall be set at a level sufficient to cover all costs for participating in the program, including any administrative costs incurred by the board to administer the program."

Adopt 16 CCR section 1357.14(b)

Purpose: The purpose of proposed section 1357.14(b) is to specify what the audit is to assess, and to require the auditor to provide a written report to the Board of their findings by a specified date. This section provides for participant confidentiality and requires the audit to identify any material deficiencies or other noncompliance with the terms of the vendor's contract with the Board. This section further requires the audit report to recommend a corrective action plan for each identified deficiency, if any.

Anticipated Benefits: The Board anticipates that this proposed section will benefit consumers, participants, and other interested parties by ensuring timely audits reviewing the PHWP's compliance with its contract with the Board, which will include compliance with the applicable statutes and regulations. Identifying areas of deficiencies will provide an opportunity for the Board and vendor to take corrective action to ensure the PHWP is effectively assisting licensees with substance abuse issues and protecting the public.

Rationale: 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 and regulations for the PHWP. BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standard #15 sets forth the requirements for auditing vendors providing monitoring services for substance abusing licensees and requires the audit report to be submitted to the Board by June 30 of each three-year cycle.

Consequently, this section is necessary to require the auditor to assess the vendor's performance in adhering to the contract requirements applicable to the program, which will include compliance with the applicable statutes and regulations, and to provide their report by June 30 of each three-year cycle as required by Uniform Standard #15. Additionally, this section is necessary to require the auditor to submit their report within 60 days of completing an off-cycle audit requested by the Board.

Moreover, this section is necessary to require the audit report to protect the confidentiality of the participants, as mandated by BPC section 2340.4(g)(2). Further this section is necessary to specify that the report shall identify material inadequacies, deficiencies, irregularities, or other noncompliance with the vendor's treatment or monitoring services that would interfere with the Board's mandate of public protection, as required by Uniform Standard #15. Further, this section is necessary to require the audit report to recommend a corrective action plan to address the deficiencies, if any. This provision is necessary to help identify ways to cure deficiencies to support the PHWP's operation and avoid the need to terminate a vendor unless it is necessary for consumer protection.

Adopt 16 CCR section 1357.14(c)

Purpose: The purpose of proposed section 1357.14(c) is to require the vendor to respond to the findings in the audit report by a specific time, and to require the Board to indicate within 60 days of receiving the response whether and when the contract with the vendor will be terminated, and the reasons for the termination, or whether the vendor will be given an opportunity to cure any deficiencies. This proposed section further requires the vendor to provide a written plan to cure deficiencies within 30 days of the Board's request. Additionally, this proposed section provides a deadline for the Board to reject, modify, or approve the vendor's plan to cure deficiencies, and indicates that the Board may extend the deadlines set forth in the section to consult with experts or for other good cause.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties by providing clarity on the vendor's and Board's required actions following receipt of an audit report.

Rationale: 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 and regulations for the PHWP. BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standard #15 sets forth the requirements for auditing vendors providing monitoring services for substance abusing licensees. BPC section 2340.4(h) indicates that the Board may terminate the contract with the vendor if the Board determines that the vendor is not in compliance with the program or the contract entered into with the Board.

Proposed section 1357.14(c) is necessary to implement the PHWP and specify the vendor's and Board's required actions following receipt of an audit report, so that the interested parties know what to expect if the auditor identifies deficiencies. The Board determined that it is necessary to provide the vendor an opportunity to respond to the auditor's findings and to cure deficiencies, if appropriate. The opportunity to respond and/or cure deficiencies, however, must be controlled to protect the public and to support participants recovering from substance abuse issues. The Board determined that it was reasonable to require the vendor to respond to an audit report by September 1, for each triennial report, which allows for 60 days to review the findings and submit a response to the Board. The vendor will be allowed 60 days to respond to an off-cycle audit report, as well. This period of time was deemed appropriate, since the vendor may have multiple contractors to work with in reviewing and responding to an audit report identifying deficiencies. Given the breadth of the PHWP, a shorter time period for response was not deemed sufficient, and a longer time period was not deemed to be in the best interest of consumer protection or the participants.

Similarly, this proposal is necessary to require the Board to indicate within 60 days of receiving the vendor's response whether and when the contract will be terminated, or whether the vendor will be given an opportunity to cure the deficiencies. The Board determined that 60 days was a reasonable time for reviewing the vendor's response and determining next steps given the significance of the decision.

Further, if the Board allows the vendor the opportunity to cure the deficiencies, this section is necessary to require the vendor to provide a written plan identifying how each deficiency will be addressed and by what time, within 30 days of the Board's request. 30 days was determined to be the appropriate time for the vendor to prepare this plan, since they would have had time to consider the auditor's findings and how to correct any substantiated deficiencies over the course of the prior communications.

Similarly, this section is necessary to require the Board to determine whether to reject, modify, or approve the vendor's plan within 30 days of receipt. 30 days was determined to be the appropriate time for the Board to respond to the vendor's plan to ensure a timely decision on next steps.

Finally, this section allows for the deadlines set forth in the section to be extended to allow time for consulting with experts or for other good cause. This proposal is necessary to provide for flexibility and extension of the deadlines when warranted for good cause.

Adopt 16 CCR section 1357.14(d)

Purpose: The purpose of proposed section 1357.14(d) is to set forth the consequence of contract termination for the vendor's failure to cure all deficiencies within the time identified in the plan approved by the Board, and to indicate that termination is within the sole discretion of the Board.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties by identifying the consequences to the vendor for failing to cure all deficiencies as agreed to in the approved plan. Identifying the consequence will foster a diligent response to correct deficiencies, if any, in the PHWP.

Rationale: 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 and regulations for the PHWP. BPC section 2340.2(e) requires the PHWP to comply with the Uniform Standards. Uniform Standard #15 sets forth the requirements for auditing vendors providing monitoring services for substance abusing licensees. BPC section 2340.4(h) indicates that the Board may terminate the contract with the vendor if the Board determines that the vendor is not in compliance with the program or the contract entered into with the Board.

This proposal is necessary to implement and provide specificity to BPC section 2340.4(h) to clarify the auditing process, the required responses thereto, and the consequence for the vendor failing to timely cure deficiencies, which includes contract termination. It is necessary to leave this decision up to the Board to weigh the consequences to consumer protection and rehabilitation of the participants of terminating the contract versus taking other remedial actions, including extending the time to cure deficiencies.

Adopt 16 CCR section 1357.14(e)

Purpose: The purpose of proposed section 1357.14(e) is to set forth the requirement for the vendor to include a written plan in its contract for transferring care and monitoring of participants if its contract with the Board is terminated.

Anticipated Benefits: The Board anticipates that this proposed section will benefit interested parties by setting forth the plan to support continued care and monitoring of participants, including a plan to transfer records to another vendor designated by the

Board to avoid disruption of services.

Rationale: BPC section 2340.4(h) indicates that the Board may terminate the contract with the vendor if the Board determines that the vendor is not in compliance with the program or the contract entered into with the Board. The abrupt termination of treatment and monitoring of licensees with substance abuse issues would be detrimental to the participants as well as the public. Having a transition plan in place will help avoid negative outcomes if the Board must terminate a contract. Consequently, this proposal is necessary to require the vendor to have, as part of its contract, a written plan for transferring care and monitoring of participants in case its contract is terminated.

Further, this proposal is necessary to require the vendor to include a plan for transferring participant or other records required to be maintained to another vendor designated by the Board. This proposal is necessary to foster a smooth transition of records to another vendor to reduce the negative impact of terminating the contract on the participants and the public.

11. Amend 16 CCR section 1361.5(c)(3)

Amend 16 CCR section 1361.5(c)(3)(G)

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.

Add 16 CCR section 1361.5(c)(3)(I)(6)

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.

Rationale: This proposed amendment is required to be consistent with the modifications the SACC made to Uniform Standard #4, effective March 2019. Because of the changes made by the SACC to Uniform Standard #4, the Board must update its regulation relating to biological fluid testing under section 1361.5(c)(3)(I) to add a new exception to the testing frequency schedule for individuals subject to licensed supervision during practice at least 50 percent per day. This additional exception is necessary for consistency with the Uniform Standards and to allow the Board to reduce the biological fluid testing frequency to a minimum of 24 times per year where the licensee meets the supervision requirement.

Underlying Data

1. SB 1177 (Galgiani, Chapter 591, Statutes of 2016).
2. Uniform Standards Regarding Substance-Abusing Healing Arts Licensees (April 2011).
3. Uniform Standards Regarding Substance-Abusing Healing Arts Licensees (March 2019).
4. October 27-28, 2016, Board Meeting Agenda, Relevant Meeting Materials, and Meeting Minutes.

5. January 11, 2017, Interested Parties Meeting Agenda, Relevant Meeting Materials
6. October 4, 2017, Interested Parties Meeting Agenda, Relevant Meeting Materials
7. October 26-27, 2017, Board Meeting Agenda, Relevant Meeting Materials, and Meeting Minutes.
8. November 7-8, 2019, Board Meeting Agenda, Relevant Meeting Materials, and Meeting Minutes.
9. August 25-26, 2022, Board Meeting Agenda, Relevant Meeting Materials, and Meeting Minutes.

Business Impact

The Board has made an initial determination that this proposed regulatory action would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. While the Board does not maintain data relating to the number or percentage of physicians who own a business, this initial assessment is based on the fact that this rulemaking is not directed toward businesses, but rather, individual substance abusing licensees.

Substance abusing licensees who are placed on probation by the Board are currently required to comply with the Uniform Standards and will continue to have to comply under the PHWP. The number of substance-abusing licensees disciplined by the Board are not expected to increase or decrease as a result of this rulemaking. Further, licensees who self-refer into the PHWP have decided to seek help for their substance abuse issues and are choosing the PHWP as their program. Regardless of what treatment and monitoring program they choose to enter, licensees would have to incur the treatment and monitoring expenses associated with such a program.

Economic Impact Assessment

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

- **It is not likely to create or eliminate jobs within the State of California.** This initial determination is based on the fact that there are vendors within the State of California with employees and contractors that already provide these services, and it is likely that one of them will contract with the Board to administer the PHWP. Further, this rulemaking will not increase or decrease the number of individuals identified as substance abusing licensees in need of monitoring and rehabilitation. Accordingly, it is not likely that this rulemaking will create or eliminate jobs in California.

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

Cost Impact on Representative Private Person or Business:

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

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

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

The Board has identified PHWP activities and costs as follows:

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

The following chart displays total PHWP activities and costs:

Medical Board of California Physician and Surgeon Health and Wellness Program - Economic Impact (costs)													
PHWP Activity	Participants/Yr.	Costs/Yr.	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total
Clinical Diagnostic	40	\$3,100*	\$124,000	\$124,000	\$124,000	\$124,000	\$124,000	\$124,000	\$124,000	\$124,000	\$124,000	\$124,000	\$1,240,000
Biological Fluid Testing	Various*	\$6,948/\$5,439***	\$277,920	\$495,480	\$713,040	\$930,600	\$1,148,160	\$1,148,160	\$1,148,160	\$1,148,160	\$1,148,160	\$1,148,160	\$9,306,000
Group Support Meetings	Various*	\$5,460	\$218,400	\$436,800	\$655,200	\$873,600	\$1,092,000	\$1,092,000	\$1,092,000	\$1,092,000	\$1,474,200	\$1,474,200	\$9,500,400
Work Monitor	Various*	\$15,600	\$624,000	\$1,248,000	\$1,872,000	\$2,496,000	\$3,120,000	\$3,120,000	\$3,120,000	\$3,120,000	\$3,120,000	\$3,120,000	\$24,960,000
In-Patient Treatment	8	\$40,000*	\$320,000	\$320,000	\$320,000	\$320,000	\$320,000	\$320,000	\$320,000	\$320,000	\$320,000	\$320,000	\$3,200,000
Total Costs:			\$1,564,320	\$2,624,280	\$3,684,240	\$4,744,200	\$5,804,160	\$5,804,160	\$5,804,160	\$5,804,160	\$6,186,360	\$6,186,360	\$48,206,400

*One-time

**Assumes 5-year probation period and 40 additional probationers per year

***Year 1 costs - \$6,948 per year & Year 2-5 costs - \$5,439 per year

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

PHWP Participation Cost Per Licensee						
Physician & Surgeon Licensee	Year 1	Year 2	Year 3	Year 4	Year 5	Total Costs
PHWP Activity Costs	\$31,108	\$26,499	\$26,499	\$26,499	\$26,499	\$137,104
PHWP with In-Patient Treatment	\$71,108	\$26,499	\$26,499	\$26,499	\$26,499	\$177,104

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

Estimated 30-Day Income Loss												
Licenses	*Income Loss Per	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total
8	\$35,583	\$284,664	\$284,664	\$284,664	\$284,664	\$284,664	\$284,664	\$284,664	\$284,664	\$284,664	\$284,664	\$2,846,640

*Average licensee salary - 30 days

Specific Technologies or Equipment

This proposed regulatory action does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome or would be more cost effective to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. The public is invited to submit such alternatives during the public comment period.

Set forth below is the alternative that considered and the reason it was rejected:

1. Do not proceed with the rulemaking. This alternative was rejected because the Board voted to move forward with establishing the PHWP as authorized by SB 1177, and regulations are needed to implement the PHWP.