MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: ATTENTION: SUBJECT: January 21, 2014 Board Members Rewrite of SB 1441 Uniform Standards Regarding Substance-Abusing Healing Arts Licensees Kerrie Webb, Senior Staff Counsel

FROM:

REQUESTED ACTION:

Review the proposed regulatory language, comments to the original proposed regulation, and staff's responses to those comments to determine if further edits need to be made.

BACKGROUND:

During the 45-day public-comment period of the rulemaking process for implementation of SB 1441 Uniform Standards Regarding Substance-Abusing Licensees, the Board received several meritorious comments on the proposed language. Additionally, a hearing was held at the October 2013 Board meeting, and further public comment was received. Following the public-comment period, significant proposed changes have been made to the draft language, and the rewrite is submitted now for review under attachment 13A. This report highlights the major changes reflected in the proposed language.

First, the proposed language drew comments that demonstrated it was difficult for readers to follow to ensure that the regulation contained the required provisions under SB 1441. Therefore, the first major change is that the language has been renumbered and reworded to conform more closely with the SB 1441 provisions, where appropriate. Please note that Uniform Standards 1, 2, and 6 are combined under 1361.5 (c)(1) (dealing with Clinical Diagnostic Evaluations and Reports; Temporary Removal From Practice) for clarity in the Board's disciplinary orders.

A second major change is that certain provisions required under SB 1441, but not appropriate to include in a disciplinary order, have been included under new proposed regulatory sections. For example, it was determined that the reporting requirements from Uniform Standards 4 and 16 were not appropriate to include in a disciplinary order, as they were directives to the Board, and not to the licensee. The absence of the reporting requirements in the prior proposed language drew negative comments from the public. Under the new rewrite, the reporting requirements are included, but in a separate proposed regulation, 16 CCR 1361.55, which is now part of this rulemaking file, and subject to public comment.

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Similarly, because these standards instruct the Board, as opposed to the licensee, on actions to be taken or requirements to be met, Uniform Standards 8 and 9 (Results of Biological Fluid Tests), 10 (Actions by Licensees and Consequences Thereof), 11 (Request to Return to Full or Partial Practice), and certain provisions of 4 and 13 (Requirements for Laboratories/Testing Locations and Specimen Collectors for Testing Substance-Abusing Licensees) are included in separate proposed sections. Thus, the Board would be required to comply with these sections, but they would not needlessly appear in a licensee's disciplinary order.

Third, the Board received comments from several professional associations and consumer groups seeking technical changes to improve the regulatory language. Each Member received a copy of all written comments. A summary of each comment and a proposed response has been prepared for the Board's review, and is attached under 13B. Those proposed changes requested through public comment, and recommended by staff for adoption by the Board, have been incorporated into the rewrite of the regulations for consideration.

Finally, there are some Uniform Standards that staff deems are not appropriate for the Board to include at this time, namely 12, dealing with an informal process for reinstatement, a mechanism that this Board does not have, and most of 13, and 14 and 15, dealing with private-sector vendors not used by this Board. At a later point, if the Board amends the disciplinary guidelines to include an informal process for reinstatement, or monitoring by a vendor, then, at that same time, the Board would have to adopt the Uniform Standards dealing with that area.

AMENDED PROPOSED REGULATIONS FOR IMPLEMENTATION OF UNIFORM STANDARDS REGARDING SUBSTANCE-ABUSING HEALING ARTS LICENSEES (SB 1441)

Modified Text

<u>Changes to the modified proposed language as presented on October 25, 2013, are</u> <u>identified by red underline for new text and blue double strikethrough for new <u>deleted text</u>. Additionally, new regulatory sections are identified by <u>highlighting</u>.</u>

Article 4 Disciplinary Guidelines and Uniform Standards for Substance-Abusing Licensees

1. Section 1361 of Title 16 of the California Code of Regulations is amended to read:

Section 1361. Disciplinary Guidelines and Exceptions for Uniform Standards Related to Substance-Abusing Licensees.

(a) In reaching a decision on a disciplinary action under the Administrative Procedures Act (Government Code Section 11400 et seq.), the Medical Board of California shall consider the disciplinary guidelines entitled "Manual of Model Disciplinary Order and Disciplinary Guidelines With Model Language" (11th Edition/2011) which are hereby incorporated by reference. Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the Medical Board of California in its sole discretion, determines that the facts of the particular case warrant such deviation – for example: the presence of mitigating factors; the age of the case; evidentiary problems.

(b) Notwithstanding subsection (a), the Board shall use the <u>Uniform Standards for Substance-Abusing Licensees as provided in Section 1361.5</u>, without deviation, for each individual determined to be a substance-abusing licensee.

(c) Nothing in this section or section 1361.5 shall be construed as a limitation on the Board's authority to seek an interim suspension order against a licensee pursuant to section 11529 of the Government Code.

2. Section 1361.5 is added to Title 16 of the California Code of Regulations to read:

1361.5. Uniform Standards for Substance-Abusing Licensees.

(a) If the licensee is to be disciplined, for unprofessional conduct involving the use of illegal drugs, the abuse of drugs and/or alcohol or both, the use of another prohibited substance as defined herein, the licensee shall be presumed to be a substance-abusing licensee for purposes of section 315 of the Code. The terms and conditions specified in subsection (c) shall be used in any probationary order of the Board affecting that licensee.

(b) Nothing in this section shall prohibit the Board from imposing additional terms or conditions of probation that are specific to a particular case or that are derived from the Board's disciplinary guidelines referenced in Section 1361 in any order that the Board determines would provide greater is necessary for public protection or to enhance the rehabilitation of the licensee.

(c) The following probationary terms and conditions, if ordered, shall be used without deviation in the case of a substance-abusing licensee:

(1) Notice of Employment Information. If a licensee whose license is on probation has an employer, the licensee shall provide to the Board the names, physical addresses, mailing addresses, and telephone numbers of all employers and supervisors and shall give specific, written consent for the Board and his or her employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring.

(1) Clinical Diagnostic Evaluations and Reports; Temporary Removal From Practice.

(A) If the Board orders a licensee who is on probation due to a substance abuse problem to undergo a clinical diagnostic evaluation, the following applies:

(i) The clinical diagnostic evaluation shall be conducted by a licensed physician and surgeon who holds a valid, unrestricted license, has three (3) years' experience in providing evaluations of physicians and surgeons with substance abuse disorders, and is approved by the Board.

(ii) The clinical diagnostic evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations.

(iii) The evaluator shall not have a current or former financial, personal, or business relationship with the licensee within the last five (5) years. The evaluator shall provide an objective, unbiased, and independent evaluation.

(iv) The clinical diagnostic evaluation report shall set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem; whether the licensee is a threat to himself or herself or others; and recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and ability to practice safely. If the evaluator determines during the evaluation process that a licensee is a threat to himself or herself or others, the evaluator shall notify the Board within 24 hours of such a determination.

(v) In formulating his or her opinion as to whether the licensee is safe to return to either part-time or full-time practice, and what restrictions or recommendations should be imposed, including participation in an inpatient or outpatient treatment program, the evaluator shall consider the following factors:

(1) License type;

(2) Licensee's history;

(3) Documented length of sobriety/time that has elapsed since substance use;

(4) Scope and pattern of substance abuse;

(5) Treatment history;

(6) Medical history;

(7) Current medical condition;

(8) Nature, duration and severity of substance abuse problem; and

(9) Whether the licensee is a threat to himself or herself or the public.

(vi) The cost of an evaluation shall be borne by the licensee.

(vii) For all evaluations, a final written report shall be provided to the Board no later than ten (10) days from the date the evaluator is assigned the matter. If the evaluator requests additional information or time to complete the evaluation and report, an extension may be granted, but shall not exceed 30 days from the date the evaluator was originally assigned the matter.

(B) Whenever the Board orders a licensee to undergo a clinical diagnostic evaluation, the Board shall order the licensee to cease practice pending the results of the clinical diagnostic evaluation and review by the Board.

(C) While awaiting the results of the clinical diagnostic evaluation, the licensee shall undergo random biological fluid testing at least two (2) times per week.

(D) The Board shall review the clinical diagnostic evaluation report within five (5) business days of receipt to determine whether the licensee is safe to return to either part-time or full-time practice and what restrictions or recommendations shall be imposed on the licensee based on the recommendations made by the evaluator. No licensee shall be returned to practice until he or she has at least 30 days of negative biological fluid tests.

(2) Clinical Diagnostic Evaluations and Reports.

(A) Whenever a licensee on probation due to a substance abuse problem is ordered to undergo a clinical diagnostic evaluation, the evaluator shall be a licensed physician and surgeon who holds a valid, unrestricted license to conduct clinical diagnostic evaluations, has three (3) years' experience in providing evaluations of physicians and surgeons with substance abuse disorders, and is approved by the Board. The evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations. The evaluator shall not have a current or former financial, personal, or business relationship with the licensee within the last five (5) years. The evaluator shall provide an objective, unbiased, and independent evaluation. The cost of an evaluation shall be borne by the licensee.

(B) For a licensee who undergoes a clinical diagnostic evaluation, the Board shall order the licensee to cease practice during the clinical diagnostic evaluation pending the results of the clinical diagnostic evaluation and review by the Board.

(C) While awaiting the results of the clinical diagnostic evaluation, the licensee shall be randomly drug tested **undergo random biological fluid testing** at least two (2) times per week.

(D) The clinical diagnostic evaluation report shall set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem, whether the licensee is a threat to himself or herself

or others, and recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and safe practice. If the evaluator determines during the evaluation process that a licensee is a threat to himself or herself or others, the evaluator shall notify the Board within 24 hours of such a determination. In determining whether the licensee is safe to return to either part-time or full-time practice and what restrictions or recommendations should be imposed, including participation in an inpatient or outpatient treatment program, the evaluator shall consider the following factors:

(i) License type, licensee's history, documented length of sobriety, scope and pattern of substance abuse, treatment history, medical history, current medical condition, nature, duration and severity of substance abuse problem, and whether the licensee is a threat to himself or herself or others.

(E) For all evaluations, a final written report shall be provided to the Board no later than ten (10) days from the date the evaluator is assigned the matter, unless the evaluator requests additional information to complete the evaluation, not to exceed 30 days.

(F) The Board shall review the clinical diagnostic evaluation report to determine whether the licensee is safe to return to either part-time or full-time practice and what restrictions or recommendations shall be imposed on the licensee based on the recommendations made by the evaluator. No licensee shall be returned to practice until he or she has at least 30 days of negative biological fluid tests.

(2) Notice of Employer or Supervisor Information. If a licensee whose license is on probation has an employer or supervisor, the licensee shall provide to the Board the names, physical addresses, mailing addresses, and telephone numbers of all employers and supervisors and shall give specific, written consent for the Board, the worksite monitor, and his or her employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring. For purposes of this section, "supervisors" shall include the Chief of Staff and the Health or Well Being Committee Chair, or equivalent, if applicable, when the licensee has medical staff privileges.

(3) Worksite Monitor Requirements and Responsibilities.

(A) If the Board determines that a worksite monitor is necessary for a particular licensee, the licensee shall, within 30 calendar days of the effective date of that determination, submit to the Board or its designee for prior approval the names of a worksite monitor(s). The worksite monitor shall meet the following criteria to be approved by the Board:

(i) The worksite monitor shall not have a current or former financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the Board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the Board; however, under no circumstances shall a licensee's worksite monitor be an employee or supervisee of the licensee.

(ii) The worksite monitor's license scope of practice shall include the scope of practice of the

licensee who is being monitored or be another physician and surgeon if no monitor with like scope of practice is available.

(iii) The worksite monitor shall have an active unrestricted license with no disciplinary action within the last five (5) years.

(B) The worksite monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and agrees to monitor the licensee as set forth by the Board.

(C) The worksite monitor shall adhere to the following required methods of monitoring the licensee:

(i) Have face-to-face contact with the licensee in the work environment on as frequent a basis as determined by the Board but not less than once per week.

(ii) Interview other staff in the office regarding the licensee's behavior, if requested by the Board.

(iii) Review the licensee's work attendance.

(D) The worksite monitor shall verbally report any suspected substance abuse to the Board and the licensee's employer within one (1) business day of occurrence. If the suspected substance abuse does not occur during the Board's normal business hours, the verbal report shall be made to the Board within one (1) hour of the next business day. A written report that includes the date, time, and location of the suspected abuse, the licensee's actions and any other information deemed important by the worksite monitor shall be submitted to the Board within 48 hours of the verbal report.

(E) The worksite monitor shall complete and submit a written report monthly or as directed by the Board. The report shall include: the licensee's name; license number; the worksite monitor's name and signature; worksite monitor's license number; worksite location(s); the dates licensee had face-to-face contact with monitor; worksite staff interviewed, if applicable; attendance report; any change in behavior and/or personal habits; any indicators that can lead to suspected substance abuse.

(F) The licensee shall execute agreements with the approved worksite monitor(s) and the Board authorizing the Board and worksite monitor to exchange information.

(G) If the monitor resigns or is no longer available, licensee shall, within 5 calendar days of such resignation or unavailability, submit to the Board the name and qualifications of a replacement monitor who will be assuming that responsibility within 15 calendar days. If licensee fails to obtain approval of a replacement monitor within 60 calendar days of the resignation or unavailability of the monitor, licensee shall receive a notification from the Board or its designee to cease the practice of medicine within three (3) calendar days after being so notified. Licensee shall cease the practice of medicine until a replacement monitor is approved and assumes monitoring responsibility.

(3) Biological Fluid Testing.

(A) The Board shall require biological fluid testing of substance-abusing licensees.

(B) For the purposes of this section, the terms "biological fluid testing" and "testing" mean the acquisition and chemical analysis of a licensee's urine, blood, breath, or hair.

(C) The Board may order a licensee to undergo a biological fluid test on any day, at any time, including weekends and holidays. Additionally, the licensee shall be subject to 52 - 104 random tests per year within the first year of probation, and 36 - 104 random tests per year for the duration of the probationary term, up to five (5) years. If there has been no positive biological fluid tests in the previous five (5) consecutive years of probation, testing may be reduced to one (1) time per month.

(D) Nothing precludes the Board from increasing the number of random tests for any reason, in addition to ordering any other disciplinary action that may be warranted.

(E) The scheduling of biological fluid testing shall be done on a random basis, preferably by a computer program, except when testing on a specific date is ordered by the Board or its designee.

(F) The licensee shall be required to make daily contact with the Board or its designee to determine if biological fluid testing is required. The licensee shall be tested on the date of the notification as directed by the Board or its designee.

(G) Prior to changing testing locations for any reason, including during vacation or other travel, alternative testing locations must be approved by the Board, and meet the requirements set forth in Section 1361.52.

(H) The cost of biological fluid testing shall be borne by the licensee.

(I) Exceptions to Testing Frequency Schedule.

(i) Previous Testing Orders/Sobriety. In cases where the Board has evidence that a licensee has participated in a treatment or monitoring program requiring random testing prior to being subject to testing by the Board, the Board may give consideration to that testing in altering the Board's own testing schedule so that the combined testing is equivalent to the requirements of this section.

(ii) Violation(s) Outside of Employment. A licensee whose license is placed on probation for a single conviction or incident or two convictions or incidents, spanning greater than seven years from each other, where those violations did not occur at work or while on the licensee's way to work, where alcohol or drugs were a contributing factor, may bypass the first-year testing frequency requirements.

(iii) Not Employed in Health Care Field. The Board may reduce the testing frequency to a minimum of 12 times per year for any licensee who is not practicing or working in any health care field. If a reduced testing frequency schedule is established for this reason, and if a licensee wants to return to practice or work in a health care field, the licensee shall notify and secure the approval of the Board. Prior to returning to any health care employment, the licensee shall be required to test at the first-year testing frequency requirement for a period of at least 60 days. At such time the person returns to employment in a health care field, if the licensee has not previously met the first-year testing frequency requirement, the licensee shall be required to test at the first-year testing frequency requirement, the licensee shall be required to test at the first-year testing frequency requirement for a period of at least 60 days. At such time the person returns to employment in a health care field, if the licensee has not previously met the first-year testing frequency requirement, the licensee shall be required to test at the first-year testing frequency requirement for a full year before he or she may be reduced to testing frequency of at least 36 tests per year.

(iv) Tolling. A Board may postpone all testing for any licensee whose probation is placed in a tolling status while the licensee is not residing in California, provided the overall length of the probationary period is also tolled. A licensee shall notify the Board upon the licensee's return to California and shall be subject to biological fluid testing as provided in this section.

(v) Substance Abuse Disorder Not Diagnosed. In cases where no current substance abuse disorder diagnosis is made, a lesser period of monitoring and biological fluid testing may be adopted by the Board, but not shall not be less than 24 times per year.

(J) Reinstatement of License or Reduction of Penalty. Nothing herein shall limit the Board's authority to reduce or eliminate the penalties herein pursuant to a petition for reinstatement or reduction of penalty filed pursuant to Government Code section 11522.

(4) Group Support Meetings.

(A) The Board may require a licensee to participate in group support meetings. The Board may impose participation in group support meetings following such recommendation by the evaluator or in a clinical diagnosis report. If the Board requires a licensee to participate in group support meetings, the following shall apply:

(B) (i) When determining the frequency of group support meetings to be attended, the Board or the evaluator shall give consideration to the following:

(1) The licensee's history;

- (2) The documented length of sobriety /time that has elapsed since substance use;
- (3) The recommendation of the clinical evaluator;
- (4) The scope and pattern of use;
- (5) The licensee's treatment history; and
- (6) The nature, duration, and severity of substance abuse.

(i) The facilitator of a group support meeting shall conform to the following requirements:

(i) (1) He or she shall have a minimum of three (3) years' experience in the treatment and rehabilitation of substance abuse, and shall be licensed or certified by the state or nationally certified organizations.

(ii) (2) He or she shall not have a current or former financial, personal, or business relationship with the licensee within the last five (5) years. A licensee's previous participation in a group support meeting led by the same facilitator does not constitute a current or former financial, personal, or business relationship.

(iii) (3) He or she shall provide to the Board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.

(iv) (4) He or she shall report a licensee's unexcused absence to the Board within 24 hours.

(iii) Any costs associated with attending and reporting on group support meetings shall be borne by the licensee.

(5) Biological Fluid Testing. The Board shall require biological fluid testing of substanceabusing licensees.

(A) For the purposes of this subsection, biological fluid testing means the acquisition and chemical analysis of a licensee's urine, blood, breath, or hair.

(B) The following standards shall apply to a licensee ordered to undergo biological fluid testing:

(i) The licensee shall be tested a minimum of 52-104 times per year for the first year of probation and at any time ordered by the Board. After the first year of probation, licensees who are practicing shall be randomly drug tested **undergo random biological fluid testing** at least 36-104 times per year, and at any time as directed by the Board.

(1) The Board may revise the frequency specified in section (i) upon a determination that the licensee is not currently employed in a health care field, the licensee suffers from a substance use or abuse disorder, or other circumstances in which a revision of the testing frequency would not impair public protection. In no case may the testing frequency be reduced below twenty-four (24) times per calendar year.

(ii) Drug <u>Biological fluid</u> testing may be required on any day, including weekends and holidays. <u>Prior to vacation or absence, alternative biological fluid testing location(s) must be</u> <u>approved by the Board.</u>

(iii) The scheduling of **biological fluid** testing shall be done on a random basis, preferably by a computer program, except when testing on a specific date is ordered by the Board.

(iv) Licensees shall be required to make daily contact with the Board to ascertain if <u>biological</u> fluid testing is required. Licensees shall be drug tested on the date of notification as directed by the Board.

(v) Licensees shall submit to all random and specifically ordered biological fluid tests.

(vi) The cost of biological fluid testing shall be borne by the licensee.

(vii) Licensees shall may elect to have the tests performed by an entity under contract with <u>a</u> laboratory or service approved in advance by the Board or by another entity, provided that the laboratory or service entity meets all the following standards:

(1) Its specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the United States Department of Transportation.

(2) It conforms to the current United States Department of Transportation Guidelines for Specimen Collection.

(3) Its testing locations comply with the Urine Specimen Collection Guidelines published by the United States Department of Transportation without regard to the type of test administered.

(4) The collection of testing specimens shall be observed.

(5) Its laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.

(6) Its collection sites submit a specimen to a laboratory within one (1) business day of receipt and all specimens collected shall be subjected to chain of custody procedures. The entity shall process and analyze the specimen and provide legally defensible test results to the Board within seven (7) <u>business</u> days of receipt of the specimen. The Board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

(5) Worksite Monitor Requirements and Responsibilities.

(A) The Board may require the use of worksite monitors. If the Board determines that a worksite monitor is necessary for a particular licensee, the licensee shall, within 30 calendar days of the effective date of that determination, submit to the Board or its designee for prior approval the name of a worksite monitor. The worksite monitor shall meet the following criteria to be approved by the Board:

(i) The worksite monitor shall not have a current or former financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the Board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the Board; however, under no circumstances shall a licensee's worksite monitor be an employee or supervisee of the licensee.

(ii) The worksite monitor's scope of practice shall include the scope of practice of the licensee being monitored, be another licensed health care professional if no monitor with like scope of practice is available, or, as approved by the Board, be a person in a position of authority who is

capable of monitoring the licensee at work.

(iii) If a licensed professional, the worksite monitor shall have an active unrestricted license with no disciplinary action within the last five (5) years.

(iv) The worksite monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and agrees to monitor the licensee as set forth by the Board.

(B) The worksite monitor shall adhere to the following required methods of monitoring the licensee:

(i) Have face-to-face contact with the licensee in the work environment on as frequent a basis as determined by the Board, but not less than once per week.

(ii) Interview other staff in the office regarding the licensee's behavior, if requested by the Board.

(iii) Review the licensee's work attendance.

(C) Reporting by the worksite monitor to the Board shall comply with the following:

(i) The worksite monitor shall verbally report any suspected substance abuse to the Board and the licensee's employer or supervisor as defined in subsection (c)(2) within one (1) business day of occurrence. If the suspected substance abuse does not occur during the Board's normal business hours, the verbal report shall be made to the Board within one (1) hour of the next business day. A written report that includes the date, time, and location of the suspected abuse, the licensee's actions and any other information deemed important by the worksite monitor shall be submitted to the Board within 48 hours of the occurrence, or the next business day.

(ii) The worksite monitor shall complete and submit a written report monthly or as directed by the Board. The report shall include the following:

(1) the licensee's name and license number;

(2) the worksite monitor's name and signature;

- (3) the worksite monitor's license number, if applicable;
- (4) the worksite location(s);
- (5) the dates the licensee had face-to-face contact with the monitor;
- (6) the names of worksite staff interviewed, if applicable;
- (7) an attendance report;

(8) any change in behavior and/or personal habits; and

(9) any indicators that can lead to suspected substance abuse.

(D) The licensee shall complete any required consent forms and execute agreements with the approved worksite monitor(s) and the Board authorizing the Board and worksite monitor to exchange information.

(E) If the monitor resigns or is no longer available, the licensee shall, within five (5) calendar days of such resignation or unavailability, submit to the Board the name and qualifications of a replacement monitor who will be assuming that responsibility within 15 calendar days. If the licensee fails to obtain approval of a replacement monitor within 60 calendar days of the resignation or unavailability of the monitor, the licensee shall receive a notification from the Board or its designee to cease the practice of medicine within three (3) calendar days after being so notified. The licensee shall cease the practice of medicine until a replacement monitor is approved and assumes monitoring responsibility.

(F) Worksite monitoring costs shall be borne by the licensee.

(6) The licensee must remain in compliance with all terms and conditions of probation. If the licensee commits a major or minor violation, as defined in Section 1361.52, the Board will execute the disciplinary actions required by that section, and impose any additional terms or conditions necessary for public protection or to enhance the rehabilitation of the licensee.

Note: Authority cited: Sections 315, 315.2, 315.4, and 2018 of the Business and Professions Code. Reference: Sections 315, 315.2, and 315.4 of the Business and Professions Code.

(6) Results of Biological Fluid Tests.

(A) If the results of a biological fluid test indicates that a licensee has used, consumed, ingested or administered to himself or herself a prohibited substance, the Board shall order the licensee to cease practice and instruct the licensee to leave any place of employment where he or she is practicing medicine or providing medical services. The Board shall also immediately notify all the licensee's employers, if any, and workplace monitor, if any, that the licensee may not provide medical services or practice medicine while the cease practice order is in effect.

(B) After the issuance of a cease practice order, the Board shall determine whether the test is in fact evidence of prohibited substance use by consulting with the specimen collector and the laboratory, communicating with the licensee, his or her treating physician(s), other health care provider, or group facilitator, as applicable.

(C) If no prohibited substance use exists, the Board shall immediately lift the cease practice order.

(D) For the purposes of this section, "prohibited substance" means an illegal or unlawful drug, a lawful drug not prescribed or ordered by an appropriately licensed health care provider for use by the licensee and approved by the Board, alcohol, or other substance.

(7) Actions by Licensees and Consequences Thereof. (A) A licensee who does any of the following shall be deemed to have committed a major violation of his or her probation:

(i) Fails to undergo a required clinical diagnostic evaluation;

(ii) Commits multiple minor violations of probation conditions and terms;

(iii) Treats a patient or patients while under the influence of drugs or alcohol;

(iv) Commits any drug or alcohol offense that is a violation of state or federal law or any regulation adopted thereto;

(v) Fails to undergo biological fluid testing when ordered;

(vi) Uses, consumes, ingests, or administers to himself or herself a prohibited substance;

(vii) Knowingly uses, makes, alters or possesses any object or product in such a way as to defraud a biological fluid test designed to detect the presence of a prohibited substance.

(B) If a licensee commits one or more major violation, the Board may take the following actions:

(i) Issue an immediate cease practice order.

(ii) Order the licensee to undergo a clinical diagnostic evaluation at the expense of the licensee. Any order issued by the Board pursuant to this subsection may state that the licensee must test negative for at least a month of continuous drug **biological fluid** testing before being allowed to resume practice.

(iii) Increase the frequency of biological fluid testing.

(C) A licensee who does any of the following shall be deemed to have committed a minor violation of his or her probation:

(i) Failure to submit required documentation to the Board in a timely manner;

(ii) Unexcused absence at required meetings;

(iii) Failure to contact a worksite monitor as required;

(iv) Failure to comply with another term or condition of his or her probation that does not impair public safety.

(D) If a licensee commits one or more minor violations, the Board may take the following actions:

(i) Issue a cease practice order;

(ii) Issue a citation and fine.

(iii) Order the licensee to undergo a clinical diagnostic evaluation at the expense of the licensee.

<u>(E) Nothing in this section shall be considered a limitation on the Board's authority to revoke</u> the probation of a licensee who has violated a term or condition of that probation.

(8) Request to Return to Full or Partial Practice.

(A) Before determining whether to authorize the return to practice after the issuance of a cease practice order or after the imposition of practice restrictions following a clinical diagnostic evaluation, the Board in conjunction with the evaluator shall ensure that the licensee meets the following criteria:

(i) A demonstration of sustained compliance with his or her current treatment or recovery program, as applicable.

(ii) A demonstration of the capability to practice medicine safely as evidenced by current worksite monitor reports, evaluations conducted by licensed health care practitioners, and any other information relating to the licensee's substance abuse and recovery therefrom.

(iii) Negative drug <u>biological fluid</u> screening reports for at least six (6) months, two (2) positive worksite monitor reports, and complete compliance with other terms and conditions of probation.

3. <u>Section 1361.51 is added to Title 16 of the California Code of Regulations to read:</u>

1361.51 Results of Biological Fluid Tests of Substance-Abusing Licensees.

(a) If the results of a biological fluid test indicate that a licensee has used, consumed, ingested or administered to himself or herself a prohibited substance, the Board shall order the licensee to cease practice and instruct the licensee to leave any place of work where he or she is practicing medicine or providing medical services. The Board shall also immediately notify all of the licensee's employers, and supervisors as defined under Section 1361.5(c)(2), if any, and work site monitor, if any, that the licensee may not provide medical services or practice medicine while the cease-practice order is in effect.

(b) A biological fluid test will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.

(c) After the issuance of a cease-practice order, the Board shall determine whether the positive biological fluid test is in fact evidence of prohibited substance use by consulting with the specimen collector and the laboratory, communicating with the licensee, his or her treating physician(s), other health care provider, or group facilitator, as applicable.

(d) If no prohibited substance use exists, the Board shall lift the cease-practice order within one (1) business day.

(e) For the purposes of this Article, "prohibited substance" means an illegal drug, a lawful drug not prescribed or ordered by an appropriately licensed health care provider for use by the licensee and approved by the Board, alcohol, or other substance the licensee has been instructed

by the Board not to use, consume, ingest, or administer to himself or herself.

(f) If the Board confirms that a positive biological fluid test is evidence of use of a prohibited substance, the licensee has committed a major violation, as defined in Section 1361.52, and the Board shall impose any or all of the consequences set forth in Section 1361.52, in addition to any other terms or conditions the Board determines are necessary for public protection or to enhance the rehabilitation of the licensee.

Note: Authority cited: Sections 315, 315.2, 315.4, and 2018 of the Business and Professions Code. Reference: Sections 315, 315.2, and 315.4 of the Business and Professions Code.

4. Section 1361.52 is added to Title 16 of the California Code of Regulations to read:

1361.52 Actions by Substance-Abusing Licensees and Consequences Thereof.

(a) A licensee who does any of the following shall be deemed to have committed a major violation of his or her probation:

(1) Fails to undergo a required clinical diagnostic evaluation;

(2) Commits multiple minor violations of probation conditions and terms;

(3) Treats a patient or patients while under the influence of a prohibited substance;

(4) Engage in any drug or alcohol related act that is a violation of state or federal law or regulation;

(5) Fails to undergo biological fluid testing when ordered;

(6) Uses, consumes, ingests, or administers to himself or herself a prohibited substance;

(7) Knowingly uses, makes, alters or possesses any object or product in such a way as to defraud, or attempt to defraud, a biological fluid test designed to detect the presence of a prohibited substance; or

(8) Fails to comply with any term or condition of his or her probation that impairs public safety.

(b) If a licensee commits a major violation, the Board will take one or more of the following <u>actions:</u>

(1) Issue an immediate cease-practice order.

(2) Order the licensee to undergo a clinical diagnostic evaluation at the expense of the licensee. Any order issued by the Board pursuant to this subsection may state that the licensee must test

negative for at least a month of continuous biological fluid testing before being allowed to resume practice.

(3) Increase the frequency of biological fluid testing.

(4) Refer the licensee for further disciplinary action, such as suspension, revocation, or other action as determined by the Board.

(c) A licensee who does any of the following shall be deemed to have committed a minor violation of his or her probation:

(1) Fails to submit required documentation to the Board in a timely manner;

(2) Has an unexcused absence at a required meeting;

(3) Fails to contact a worksite monitor as required; or

(4) Fails to comply with any term or condition of his or her probation that does not impair public safety.

(d) If a licensee commits a minor violation, the Board will take one or more of the following actions:

- (1) Issue a cease-practice order;
- (2) Order practice limitations;
- (3) Order or increase supervision of licensee;
- (4) Order increased documentation;
- (5) Issue a citation and fine, or a warning letter;

(6) Order the licensee to undergo a clinical diagnostic evaluation at the expense of the licensee;

(7) Take any other action as determined by the Board.

(E) Nothing in this section shall be considered a limitation on the Board's authority to revoke the probation of a licensee who has violated a term or condition of that probation.

Note: Authority cited: Sections 315, 315.2, 315.4, and 2018 of the Business and Professions Code. Reference: Sections 315, 315.2, and 315.4 of the Business and Professions Code.

5. <u>Section 1361.53 is added to Title 16 of the California Code of Regulations to read:</u>

1361.53 Request by a Substance-Abusing Licensee to Return to Practice.

(a) Before determining whether to authorize the return to practice after the issuance of a ceasepractice order or after the imposition of practice restrictions following a clinical diagnostic evaluation, the Board in conjunction with the evaluator shall ensure that the licensee meets the following criteria:

(1) A demonstration of sustained compliance with his or her current treatment or recovery program, as applicable;

(2) A demonstration of the capability to practice medicine safely as evidenced by current worksite monitor reports (if currently being monitored), evaluations conducted by licensed health care practitioners, and any other information relating to the licensee's substance abuse and recovery therefrom; and

(3) Negative biological fluid testing reports for at least six (6) months, two (2) positive worksite monitor reports (if currently being monitored), and complete compliance with other terms and conditions of probation.

Note: Authority cited: Sections 315, 315.2, 315.4, and 2018 of the Business and Professions Code. Reference: Sections 315, 315.2, and 315.4 of the Business and Professions Code.

6. Section 1361.54 is added to Title 16 of the California Code of Regulations to read:

<u>1361.54</u> Requirements for Laboratories/Testing Locations and Specimen Collectors for Testing Substance-Abusing Licensees.

(a) Licensees shall contract with a laboratory or service approved in advance by the Board, provided that the laboratory or service meets all the following standards:

(1) Its specimen collectors shall either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the United States Department of Transportation.

(2) Its specimen collectors shall conform to the current United States Department of Transportation Specimen Collection Guidelines.

(3) Its testing locations shall comply with the Urine Specimen Collection Guidelines published by the United States Department of Transportation without regard to the type of test administered.

(4) Its specimen collectors shall observe the collection of testing specimens.

(5) Its laboratories shall be certified and accredited by the U.S. Department of Health and Human <u>Services.</u>

(6) Its testing locations shall submit a specimen to a laboratory within one (1) business day of receipt and all specimens collected shall be handled pursuant to chain of custody procedures. The laboratory shall process and analyze the specimen and provide legally defensible test results to the Board within seven (7) business days of receipt of the specimen. The Board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

(7) Its testing locations shall possess all the materials, equipment and technical expertise necessary in order to test every licensee for which it is responsible on any day of the week.

(8) Its testing locations shall be able to scientifically test for urine, blood, and hair specimens for the detection of alcohol, illegal, and controlled substances.

(9) It must have testing sites that are located throughout California.

(10) It must have an automated 24-hour toll-free telephone system and/or a secure on-line computer database that allows the licensee to check in daily for testing.

(11) It must have a secure, HIPAA-compliant website or computer system to allow staff access to drug test results and compliance reporting information that is available 24 hours a day.

(12) It shall employ or contract with toxicologists that are licensed physicians and have knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate laboratory biological fluid test results, medical histories, and any other information relevant to biomedical information.

(13) A toxicology screen will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.

Note: Authority cited: Sections 315, 315.2, 315.4, and 2018 of the Business and Professions Code. Reference: Sections 315, 315.2, and 315.4 of the Business and Professions Code.

7. Section 1361.55 is added to Title 16 of the California Code of Regulations to read:

1361.55 Reporting Requirements Relating to Substance-Abusing Licensees.

(a) The Board shall report the following information on a yearly basis to the Department of Consumer Affairs and the Legislature as it relates to licensees with substance abuse problems who are on probation:

(1) Number of probationers whose conduct was related to a substance abuse problem;

- (2) <u>Number of relapses (break in sobriety);</u>
- (3) Number of cease-practice orders;
- (4) <u>Number of suspensions;</u>
- (5) <u>Number of major violations; nature of violation and action taken;</u>
- (6) Number of petitions to revoke probation filed; and
- (7) Number of licensees who successfully completed probation.

(b) For each reporting category described in subsection (a), the Board shall identify the licensing category, and the specific substance abuse problem (i.e., cocaine, alcohol, Demorol, etc.).

(c) If the reporting data indicates that licensees in specific licensing categories or with specific substance abuse problems have either a higher or lower probability of success, that information shall be taken into account when determining the success of terms and conditions of probation. The information may also be used to determine the risk factor when the Board is determining whether a license should be revoked or placed on probation.

(d) The Board shall use the following criteria to determine if its terms and conditions of probation protects patients from harm and is effective in assisting its licensees in recovering from substance abuse problems in the long term:

(1) One hundred percent of licensees whose licenses were placed on probation as a result of a substance abuse problem successfully completed probation, or had their licenses to practice revoked or surrendered on a timely basis based on noncompliance with terms and conditions of probation.

(2) At least 75 percent of licensees who successfully completed probation did not have any substantiated complaints related to substance abuse for at least five (5) years after completion.

(e) For purposes of measuring outcomes and effectiveness relating to biological fluid testing as described in Section 1361.5(c)(3), the Board shall collect and report historical data (as available) and post-implementation data as follows:

(1) Historical Data. The Board should collect the following historical data (as available) for a period of two years prior to implementation of the Uniform Standards for Substance-Abusing Licensees, for each person subject to testing for banned substances, who has done any of the following:

(A) Tested positive for a banned substance;
(B) Failed to appear or call in for testing on more than three occasions;
(C) Failed to pay testing costs; or
(D) Given a diluted or invalid specimen.

(2) Post implementation Data – Three Years

The Board shall collect data annually for a period of three years following implementation of the Uniform Standards for Substance-Abusing Licensees for every licensee subject to testing for banned substances pursuant to Section 1361.5(c)(3). The data collected shall be reported to the Department of Consumer Affairs and the Legislature, upon request, and shall include, but may not be limited to:

(A) Licensee identification;

(B) License type;

(C) Probation effective date;

(D) General range of testing frequency for each licensee;

(E) Dates testing requested;

(F) Dates tested;

(G) Identity of the entity that performed each test;

(H) Date(s) licensee tested positive;

(I) Date(s) Board was informed of positive test(s);

(J) Date(s) of questionable tests (e.g. dilute, high levels);

(K) Date(s) Board was notified of questionable test(s);

(L) Identification of substances detected or questionably detected;

(M) Date(s) licensee failed to appear for testing;

(N) Date(s) Board notified of licensee's failure to appear;

(O) Date(s) licensee failed to call in for testing;

(P) Date(s) Board was notified that licensee failed to call in for testing;

(Q) Date(s) licensee failed to pay for testing;

(R) Date(s) licensee was removed/suspended from practice (identify which); and

(S) Final outcome and effective date (if applicable).

Note: Authority cited: Sections 315, 315.2, 315.4, and 2018 of the Business and Professions Code. Reference: Sections 315, 315.2, and 315.4 of the Business and Professions Code.

Suggested Responses to Comments Received During the 45-day Comment Period and at the October 25, 2013 Hearing on Regulations to Implement SB 1441 – Uniform Standards for Substance-Abusing Licensees

1. <u>Comments by Shannon K Robinson, M.D.</u>

Comment 1.1 – Shannon K. Robinson, M.D., stated that the proposed regulation does not provide clear timelines for the Board to complete adjudication, which can result in physicians continuing to work when they could still be doing harm to patients, or, alternatively, the physician may not be working, and may not be able to get a job while waiting for the Board's decision.

Suggested Response 1.1 – Staff recommends rejecting this comment, as Dr. Robinson is directing her comments to the enforcement timelines that take place before the imposition of disciplinary action. The proposed regulations come into play after a determination has been made that discipline as a substance-abusing licensee is warranted.

2. <u>Comments by the California Medical Association (CMA) and California Academy</u> <u>of Family Physicians (CAFP) (where they joined CMA's Comments)</u>

Comment 2.1 –CMA and CAFP expressed concern about the directive to promulgate regulations to implement the SB 1441 standards, which they say are unnecessarily punitive, can further limit access to care by qualified physicians, and which were not developed through a standard regulatory process with full public comment and review by the appropriate state agencies. CMA stated that "Approving regulations simply because they are based on standards developed by another state agency without regard to whether the regulations would be appropriate for physicians and surgeons would not protect consumers and potentially would violate the APA." This was reiterated by Yvonne Choong for CMA at the hearing.

Suggest Response 2.1 – Staff recommends rejecting this comment. While the Board is required by statute to promulgate these regulations, the Board is not simply doing a blanket adoption of regulations developed by another state agency. The Board is engaging in open, public debate about the proposed regulations, and is tailoring the provisions to be workable for the Board and its licensees. Provisions that are not currently applicable to the Board, i.e., those that deal with vendors, are not included in the draft regulations.

Comment 2.2 - CMA and CAFP asked that, with regard to clinical diagnostic evaluations and reports, the licensee be provided with the evaluation report at the same time it is provided to the Board given the potential impact of the findings of the report on a licensee's practice (referring to former section 1361.5(c)(2)(E), which is now 1361.5(c)(1)(A)(vii)).

Suggested Response 2.2 – Staff recommends rejecting this comment, as the Board complies with the provisions of the Information Practices Act, specifically Civil Code section 1798.40, when determining whether and when to release a report that pertains to the physical or psychological condition of the licensee.

Comment 2.3 – CMA asserts that the section addressing worksite monitor requirements and responsibilities is unclear as it implies that the worksite monitor should be practicing in the same specialty as the monitored licensee (referring to former section 1361.5(c)(3)(i)), which is now 1361.5(c)(5)(A)(ii). CMA stated that while this would be appropriate if the worksite monitor is expected to evaluate the quality of care provided, it is not necessary if the monitor is evaluating on non-clinical issues, such as attendance and general sobriety.

Suggested Response 2.3 – Staff recommends accepting this comment, and believes that CMA's concerns have been fully addressed by the proposed rewrite under 1361.5(c)(5)(A)(ii):

The worksite monitor's scope of practice shall include the scope of practice of the licensee being monitored, be another licensed health care professional if no monitor with like scope of practice is available, or, as approved by the Board, be a person in a position of authority who is capable of monitoring the licensee at work.

Comment 2.4 – CMA expressed concern that the provisions dealing with group support meetings may be overly burdensome, because it is unclear if previous participation in a support group would prohibit the licensee from attending a group operated by the same facilitator, since the draft regulation prohibits the licensee and facilitator from having a current or former financial, personal, or business relationship within the last five years (referring to section 1361.5(c)(4)).

Suggested Response 2.4 – Staff recommends accepting this comment, and has redrafted the proposed language under 1361.5(c)(4)(A)(ii)(2) to state:

He or she shall not have a current or former financial, personal, or business relationship with the licensee within the last five (5) years. A licensee's previous participation in a group support meeting led by the same facilitator does not constitute a current or former financial, personal, or business relationship.

Comment 2.5 – CMA and CAFP asked for clarification under Results of Biological Fluid Tests on the time frame in which the cease practice order should be removed if no prohibited substance use exists, including when related public disclosures will be removed, as "immediately" is vague (referring to former section 1361.5(c)(6)(C), which is now 1361.51(d)).

Suggested Response 2.5 – Staff recommends accepting this comment, and believes the issue is resolved under the proposed new language under 1361.51(d), which states: "If no prohibited substance use exists, the Board shall lift the cease practice order within one (1) business day."

Comment 2.6 – CMA asked for clarification of what "other substance" would be under

Results of Biological Fluid Tests (referring to former section 1361.5(c)(6)(D), which is now 1361.51(e)).

Suggested Response 2.6 – Staff recommends accepting this comment and has clarified the term "prohibited substance," in the new language under 1361.51(e), which states:

For the purposes of this Article, "prohibited substance" means an illegal drug, a lawful drug not prescribed or ordered by an appropriately licensed health care provider for use by the licensee and approved by the Board, alcohol, or other substance the licensee has been instructed by the Board not to use, consume, ingest, or administer to himself or herself.

The reason it is necessary to include "other substances" is to cover activities that do not fit well within a more narrow definition, such as "huffing," which involves the inhalation of household or industrial chemical products, i.e., paint, glue, gasoline, etc., which can cause intoxication, hallucinations, and other impairment.

Comment 2.7 – CMA and CAPF asked for clarification under Actions by Licensees and Consequences Thereof, where it states that a licensee may not treat a patient while under the influence of drugs or alcohol. They are concerned that proper use of prescribed medication could be lumped into this section as it is worded (referring to former section 1361.5(c)(7)(a)(iii), which is now section 1361.52(a)(3)).

Suggested Response 2.7 – Staff recommends accepting this comment, and believes the issue has been clarified with the proposed new language under 1361.52(a)(3), which states, in pertinent part:

(a) A licensee who does any of the following shall be deemed to have committed a major violation of his or her probation:

. . .

(3) Treats a patient or patients while under the influence of a prohibited substance.

3. <u>Comments by Consumers Union Safe Patient Project (CUSPP)</u>

Comment 3.1 – CUSPP stated that the Board should amend the proposed regulations to include all elements of the Uniform Standards.

Suggested Response 3.1 – Staff recommends rejecting this comment. There are some Uniform Standards that staff deems are not appropriate for the Board to include at this time. For example, most of Uniform Standards #13, and #14 and #15, dealing with private-sector vendors not used by the Board, should not be included. At a later point, if the Board amends the disciplinary guidelines to include monitoring by a vendor, then, at that same time, the Board would have to adopt the Uniform Standards dealing with vendors.

Comment 3.2 – CUSPP stated that the proposed regulation failed to specify the requirement of random drug testing in the first year of probation.

Suggested Response 3.2 – Staff recommends rejecting this comment. This provision was specifically included in section 1361.5(c)(5)(B)(i), and calls for drug testing a minimum of 52-104 times per year. Additionally, subsection (B)(iii) required that the scheduling of biological fluid testing be done on a random basis. Under the new rewrite, these provisions are included under 1361.5(c)(3)(C).

Comment 3.3 – CUSPP stated that the proposed regulation failed to specify that the Board may order a licensee to undergo a drug test at any time.

Suggested Response 3.3 – Staff recommends rejecting this comment. This provision was specifically included in section 1361.5(c)(5)(B)(i). Under the new rewrite, it is included under 1361.5(c)(3)(C).

Comment 3.4 – CUSPP stated that the proposed regulation failed to indicate that nothing precludes the Board from increasing the number of random tests for any reason.

Suggested Response 3.4 – Staff recommends rejecting this comment. This provision was specifically included in section 1361.5(c)(5)(B)(i). Under the new rewrite, these provisions are included under 1361.5(c)(3)(D).

Comment 3.5 – CUSPP stated that the proposed regulation failed to indicate that when the Board finds or has suspicion that a licensee has committed a violation of the testing program or who has committed a major violation, the Board may reestablish the testing cycle, and place the licensee in the most rigorous testing category, in addition to imposing any other disciplinary action that may be pursued.

Suggested Response 3.5 – Staff recommends rejecting this comment. This provision was specifically included in section 1361.5(c)(5)(B)(i), and under (7)(B)(iii). Moreover, pursuant to 1361.5(b) nothing in this section prohibits the Board from imposing additional terms or conditions as warranted. Under the new rewrite, these provisions are included under 1361.52(b)(3) and (4). Among other things, if a licensee uses a prohibited substance, fails to undergo testing when ordered, or attempts to defraud a biological fluid test, the licensee has committed a major violation, and the Board will take action pursuant to 1361.52(b).

Comment 3.6 – CUSPP stated that the proposed regulation failed to include monthly drug testing following five years of successful testing.

Suggested Response 3.6 – Staff recommends rejecting this comment. This provision was specifically included in section 1361.5(c)(5)(B)(i)(1). Under the new rewrite, these provisions are included under 1361.5(c)(3)(C).

Comment 3.7 – CUSPP stated that the proposed regulation failed to identify the exceptions to the testing frequency schedule, including the following: 1) testing parameters for physicians whose

violations did not occur at work, and where drugs/alcohol was a contributing factor; 2) tolling in cases where a licensee is not employed in the healthcare field or has left the state; and 3) testing in cases where no current substance use disorder diagnosis is made.

Suggested Response 3.7 – Staff recommends rejecting this comment. Exceptions to testing frequency were included in section 1361.5(c)(5)(B)(i)(1). Under the new rewrite, these provisions are included under 1361.5(c)(3)(I).

Comment 3.8 – CUSPP stated that the proposed regulation failed to include the process regarding petitions for reinstatement.

Suggested Response 3.8 – Staff recommends accepting this comment, although it is simply a restatement of the Board's authority to accept petitions for reinstatement pursuant to a petition filed under Government Code section 11522. Under the new rewrite, this provision is included under 1361.5(c)(3)(J).

Comment 3.9 – CUSPP stated that the proposed regulation failed to include reporting requirements regarding physicians who tested positive for a banned substance; failed to appear or call in for testing; failed to pay testing costs, and numerous other data requirements.

Suggested Response 3.9 – Staff recommends accepting this comment. Under prior drafts, the reporting requirements were not included since they were directives to the Board, and were not to be included in a licensee's disciplinary order. Under the new rewrite, these provisions are broken out into a separate regulation under 1361.55(e).

Comment 3.10 – CUSPP stated that the proposed regulation does not indicate that failure to complete a board-ordered program is required to be considered a major violation.

Suggested Response 3.10 – Staff recommends rejecting this comment. The Board no longer has a diversion program, and will not be ordering any licensee into any particular type of treatment/monitoring program.

Comment 3.11 – CUSPP stated that the proposed regulation does not indicate that consequences for minor violations include: practice limitations; supervision; increased documentation; and issuance of a citation, fine or warning.

Suggested Response 3.11 – Staff recommends accepting this comment. Under the new rewrite, these provisions are included under 1361.52(d).

Comment 3.12 – CUSPP stated that the proposed regulation does not include criteria that a licensee must meet in order to petition for reinstatement of his or her license.

Suggested Response 3.12 – Staff recommends rejecting this comment. Uniform Standard #12 addresses an "informal" request/petition for reinstatement. The Board does not have an informal process for considering requests/petitions for reinstatement. The licensee must file a petition for reinstatement pursuant to Government Code section 11522. The new rewrite states this requirement under section 1361.5(c)(3)(J).

Comment 3.13 – CUSPP stated that the proposed regulation does not include required timing for a vendor to report major and minor violations, and does not include a list of nine requirements to be met by specimen collectors.

Suggested Response 3.13 – Staff recommends accepting this comment as it relates to specimen collectors only. The Board does not use vendors in other capacities. The new rewrite includes requirements relating to specimen collectors under section 1361.54.

Comment 3.14 – CUSPP stated that the proposed regulation does not include public disclosure requirements related to physicians in diversion programs.

Suggested Response 3.14 – Staff recommends rejecting this comment. The Board does not use a private-sector vendor that provides diversion services, therefore Uniform Standard #14 does not apply at this time, and the regulation should not include it.

Comment 3.15 – CUSPP stated that the proposed regulation does not include audit requirements for private-sector vendors.

Suggested Response 3.15 – Staff recommends rejecting this comment. The Board does not use a private-sector vendor that provides diversion services, therefore Uniform Standard #15 does not apply at this time, and the regulation should not include it.

Comment 3.16 – CUSPP stated that the proposed regulation does not include the public reporting requirements under Uniform Standard #16.

Suggested Response 3.16 – Staff recommends accepting this comment. Under prior drafts, the reporting requirements were not included since they were directives to the Board, and were not to be included in a licensee's disciplinary order. Under the new rewrite, these provisions are broken out into a separate regulation under 1361.55.

4. <u>Comments by the Wellness Committee of Northern California Psychiatric Society</u> (WCNCPS)

Comment 4.1 – WCNCPS commented that the term "substance-abusing licensees" is an awkward phrase that implies prejudice against former substance abusers.

Suggested Response 4.1 – Staff recommends rejecting this comment. The term "substance-abusing licensees" is consistent with the language in Business and Professions Code section 315.

Comment 4.2 –WCNCPS stated that imposing "uniform standards" "without deviation" abolishes the individualization of licensees with a history of substance abuse. They further state that not all licensees need the same amount of remedial activities, and that to have the same uniform standards apply to someone who has been in recovery for years as someone just entering recovery does not make sense.

Suggested Response 4.2 – Staff recommends accepting this comment, in part, and has rewritten 1361.5(c) to provide clarification as follows: **"The following probationary terms and conditions, <u>if ordered</u>, shall be used without deviation in the case of a substance-abusing licensee" (emphasis added). Under Business and Professions Code section 315, the Board's flexibility in how the Uniform Standards are applied are limited, however, not all of the terms and conditions have to be applied in every case. For example, the Board is not required to order every substance-abusing licensee to go to group support meetings, or to have a worksite monitor, but if the Board does order these terms and conditions, the order must comply with the provisions of the 1361.5. Every substance-abusing licensee will have to undergo biological fluid testing, but there are some exceptions to the testing frequency that factor in the licensee's particular situation under 1361.5(c)(3)(I). Additionally, when appropriate, licensees may petition for modification of termination of probation pursuant to Business and Professions Code section 2307.**

Comment 4.3 –WCNCPS stated with regard to 1361.5(c)(1) (now section 1361.5(c)(2)) on Notice of Employment Information, that the presiding judge at the hearing usually comments on how extensively one must inform employers and supervisors of the discipline and history of substance abuse. For the Board to require all employers and supervisors to be given personal information and to be possibly contacted by the Board, abolishes discretion between the licensee and the Board's probation officer.

Suggested Response 4.3 – Staff recommends rejecting this comment, as the section on Notice of Employer or Supervisor Information is consistent with the terms of Uniform Standard #3, and provides an important consumer safe guard.

Comment 4.4 –WCNCPS stated with regard to clinical diagnostic evaluations and cease-practice orders (formerly under 1361.5(c)(2)(A and B), now 1361.5(c)(1)), that while the Board should have the right to require a clinical diagnostic evaluation, it should not necessarily order the licensee to cease practicing during the evaluation process. Any order to cease practice should come as a result of the evaluation.

Suggested Response 4.4 – Staff recommends rejecting this comment. The language is consistent with Uniform Standards #1 and #2. The cease-practice order comes into play when the licensee is to be disciplined for unprofessional conduct involving the use of illegal drugs, the abuse of drugs and/or alcohol, or the use of another prohibited substance. A cease-practice order is also imposed if the results of a biological fluid test indicates that a licensee has used a prohibited substance. The use of a cease-practice order under these conditions is an important tool for consumer protection.

Comment 4.5 - WCNCPS stated with regard to worksite monitors (formerly under 1361.5(c)(3)(A), now 1361.5(c)(5)), that the requirements of the worksite monitor are unreasonable and unworkable, and that not many physicians, if any, would agree to take on the task of monitoring. It turns the monitor into a policeman. The extent of the monitor's duties should be individualized case by case.

Suggested Response 4.5 – Staff recommends rejecting this comment. The language is consistent with Uniform Standard #7, and provides for important monitoring of licensees in recovery from alcohol or substance abuse. Moreover, under the new rewrite, the qualifications of a monitor

have been broadened, so that if no monitor with like scope of practice is available, the monitor may be a person in a position of authority who is capable of monitoring the licensee at work, and who is approved by the Board.

Comment 4.6 - WCNCPS stated with regard to support group leaders under 1361.5(c)(4), requiring leaders to report an unexcused absence to the Board within 24 hours would destroy the therapeutic process. They suggested changing the language to require the leader to report "a pattern of disturbing unexcused absences."

Suggested Response 4.6 – Staff recommends rejecting this comment. The language is consistent with Uniform Standard #5, and is an important consumer protection tool to ensure that the licensee is being compliant with the terms of the disciplinary order. The 24-hour reporting requirement for an unexcused absence will allow the probation monitor to check in with the licensee, take action if substance use is suspected, and impose consequences for a violation under 1361.52.

Comment 4.7 - WCNCPS stated with regard to biological fluid testing (formerly under 1361.5(c)(5)(B)(i), now 1361.5(c)(3)(C)), that testing twice per week is unreasonable, is not based on science, and is an undue hardship to the licensee, as these tests are expensive. They contended that testing once a week would suffice, and that testing on Sundays is unreasonable.

Suggested Response 4.7 – Staff recommends rejecting this comment. The language is consistent with Uniform Standard #4, and provides important flexibility with the randomized testing requirement. Some substances can clear from the body within 3 days, so the possibility of being tested twice a week, including on weekends and on holidays, is an important deterrent and consumer-protection safeguard.

Comment 4.8 – WCNCPS objected to the Board issuing a cease-practice order following a positive test (referring to former section 1361.5(c)(6), now 1361.51). They pointed out that false positives are common, and it can take a long time to determine that a positive test is due to actual use. Interrupting the licensee's practice, and notifying employers and supervisors can ruin the licensee's career.

Suggested Response 4.8 – Staff recommends rejecting this comment. The language is consistent with Uniform Standard #8. Moreover, labs are required to provide legally-defensible test results within seven business days pursuant to proposed section 1361.54(a)(6). If the Board confirms that no prohibited substance was used, the cease-practice order must be lifted within one business day pursuant to proposed section 1361.51(a). Moreover, these provisions come into play after the individual has been confirmed to be a substance-abusing licensee. Accordingly, a positive test must be acted upon with consumer protection being paramount.

Comment 4.9 – WCNCPS stated that no mention is made of a requirement that a licensee be tested while on vacation.

Suggested Response 4.9 – Staff recommends accepting this comment, and the requirement that a licensee be tested while on vacation is included in the new rewrite under 1361.5(c)(3)(G).

5. <u>Comments by the California Hospital Association (CHA)</u>

Comment 5.1 –CHA recommended that the regulation be amended to require notice be provided to the licensee's employer and any medical staff(s) to which the licensee is a member with clinical privileges.

Suggested Response 5.1 – Staff recommends accepting this comment. Under 1361.5(c)(2), the new rewrite includes the Chief of Staff and the Health or Well Being Committee Chair, or equivalent, under the definition of "supervisors," when the licensee has medical staff privileges.

Comment 5.2 – CHA recommended that the regulation be amended to require direct notice by the licensee to their employers, supervisors, Chiefs of Staff, and Well Being Committee Chairs, as applicable, instead of simply relaying contact information and a consent form to the Board.

Suggested Response 5.2 – Staff recommends rejecting this comment. The current draft language is consistent with Uniform Standard #3. The Board may require the licensee to directly notify his or her employers under the disciplinary guidelines. The purpose of this uniform standard is to obtain specific consent from the licensee to permit the Board and the licensee's employers, supervisors, etc., to be in communication with each other as needed to promote public protection and the rehabilitation of the licensee.

Comment 5.3 – CHA recommended that the regulation be amended to exempt the monitored licensee from the medical staffs' hearing rights, and include certain protections from liability against the hospital and its medical staff whenever concurrent restrictions are imposed on a monitored licensee who is also a member of a hospital's medical staff with privileges.

Suggested Response 5.3 – Staff recommends rejecting this comment. Hearing rights are governed by separate statutes, including Business and Professions Code sections 809.2 and 809.3, and cannot be changed by the proposed regulations.

6. Joint Comments by the California Public Protection and Physician Health (CPPPH), California Society of Addiction Medicine (CSAM), California Hospital Association (CHA), and California Psychiatric Association (CPA)

Comment 6.1 – CPPPH, CSAM, CHA, and CPA jointly recommended that the regulation be amended to require notice be provided to the licensee's employer and any medical staff(s) to which the licensee is a member with clinical privileges.

Suggested Response 6.1 – Staff recommends accepting this comment. Under 1361.5(c)(2), the new rewrite includes the Chief of Staff and the Health or Well Being Committee Chair, or equivalent, under the definition of "supervisors," when the licensee has medical staff privileges.

Comment 6.2 – CPPPH, CSAM, CHA, and CPA jointly recommended that the regulation be amended to require direct notice by the licensee to their employers, supervisors, Chiefs of Staff, and Well Being Committee Chairs, as applicable, instead of simply relaying contact information and a consent form to the Board.

Suggested Response 6.2 – Staff recommends rejecting this comment. The current draft language is consistent with Uniform Standard #3. The Board may require the licensee to directly notify his or her employers under the disciplinary guidelines. The purpose of this uniform standard is to obtain specific consent from the licensee to permit the Board and the licensee's employers, supervisors, etc., to be in communication with each other as needed to promote public protection and the rehabilitation of the licensee.

Comment 6.3 – CPPPH, CSAM, CHA, and CPA jointly pointed out that the Board can order a licensee who is required to undergo a clinical diagnostic evaluation to cease practice and be randomly drug tested at least twice a week while awaiting the results. Further, while the evaluator is required to submit a full written report no later than 10 days from being assigned the evaluation (or within 30 days, if an extension is granted), there is no requirement for review and determination by the Board within a specified time. They stated that such a burden should not be placed on the licensee without a specific rule governing the length of time before it would be either continued for cause or lifted. They recommended a time frame of five business days for Board review and determination.

Suggested Response 6.3 – Staff recommends accepting this comment, and has incorporated a time frame for the Board to review the clinical evaluation report under 1361.5(c)(1)(D) as follows: "The Board shall review the clinical diagnostic evaluation report within five (5) business days of receipt to determine whether the licensee is safe to return to either part-time or full-time practice..."

Comment 6.4 – CPPPH, CSAM, CHA, and CPA jointly contended that the requirements for a worksite monitor may make it inordinately difficult for the licensee to find a qualified individual to fill the role. Without someone to fill the role, a licensee who is deemed safe to practice, will not be permitted to practice.

Suggested Response 6.4 - Staff recommends accepting this comment, and has drafted amended language under 1361.5(c)(5)(A)(ii):

The worksite monitor's scope of practice shall include the scope of practice of the licensee being monitored, be another licensed health care professional if no monitor with like scope of practice is available, or, as approved by the Board, be a person in a position of authority who is capable of monitoring the licensee at work.

Comment 6.5 – CPPPH, CSAM, CHA, and CPA jointly opposed the requirement that "the worksite monitor shall verbally report any *suspected* (emphasis added) substance abuse to the Board and the licensee's employer within one business day of occurrence." They believe that suspected substance abuse should not be reported, and instead, the monitor should be able to require the licensee to submit to a biological fluid test within four hours.

Suggested Response to 6.5 – Staff recommends rejecting this comment. The current draft language is consistent with Uniform Standard #7, and provides important information to the Board and the licensee's employers and supervisors, so that any necessary safeguards can be put in place while awaiting a legally defensible biological fluid test.

Comment 6.6 – CPPPH, CSAM, CHA, and CPA jointly stated that a cease-practice order should only be imposed once there is confirmation of a legally-defensible report from the testing entity indicating that the licensee has used a prohibited substance, and the Board should not take such action upon initial receipt of a positive test.

Suggested Response to 6.6 – Staff recommends rejecting this comment. The current draft language is consistent with Uniform Standard #8, and it is imperative for consumer protection for the Board to be able to issue a cease-practice order immediately upon receiving a positive test result for a licensee who has had a history of alcohol or substance abuse.

Comment 6.7 – CPPPH, CSAM, CHA, and CPA jointly expressed concern with the section that says, "if no prohibited substance use exists, the Board shall immediately lift the cease-practice order," because the term "immediately" is not defined.

Suggested Response 6.7 – Staff recommends accepting this comment, and believes the issue is resolved under the proposed new language under 1361.51(d), which states: "If no prohibited substance use exists, the Board shall lift the cease-practice order within one (1) business day."

Comment 6.7 – CPPPH, CSAM, CHA, and CPA jointly expressed concern regarding former section 1361.5(c)(8)(A) (now section 1361.53(a)(3)) as it requires the licensee to have negative biological fluid testing reports for at least six months and two positive worksite monitor reports before he or she is eligible to return to full or partial practice. They stated that temporarily closing a practice for longer than three months may result in permanent closure, poor continuity of patient care, and loss of medical skills. They argued that return to practice should be based on an assessment by a licensed healthcare practitioner and not on arbitrary durations. They also pointed out that physicians seeking to return to work should not be required to produce a worksite monitor report if they have not been working, as they would not have such a report.

Suggested Response 6.7 – Staff recommends rejecting the comment, in part, regarding the objection to the requirement for six months of negative testing before a licensee is authorized to return to full or part-time practice. This requirement is consistent with Uniform Standard #11, and is an important consumer-protection provision.

Staff recommends accepting the comment with regard to worksite monitor reports, and has amended the language under the rewrite to require: "...two (2) positive worksite monitor reports (if currently being monitored)..."

7. <u>Comments by the California Psychiatric Association (CPA)</u>

Comment 7.1 – CPA pointed out the limitations of SB 1441 in addressing substance-abusing licensees with co-occurring mental disorders. They pointed out that if both the substance-abuse issue and the mental disorder are not addressed concurrently and in an integrated fashion, then the treatment prognosis for the licensee is diminished and the goals are undermined. They stated that guidelines and standards for co-occurring mental disorders need to be developed and adopted.

Proposed Response 7.1 – Staff recommends rejecting this comment, as the proposed regulations do not impair concurrent treatment for co-occurring mental disorders. The Board continues to have authority to order a psychiatric evaluation and require psychotherapy when necessary.

Comment 7.2 – CPA pointed out that Article 2, starting at section 1357 contains regulations relating to the Impaired Physician Diversion Program, which no longer exists, and suggested that they be repealed.

Proposed Response 7.2 – While this comment is not directed to the current proposed regulation, staff agrees that the regulations relating to the Impaired Physician Diversion Program should be repealed, and that will occur via a different regulatory package.

Comment 7.3 – CPA contended that the regulations to implement SB 1441 authorize the Board to issue orders against licensees to restrict, suspend or cease practice, but do not provide the affected licensee with any right to notice or hearing prior to requiring of restriction or cessation of practice.

Proposed Response 7.3 – Staff recommends rejecting this comment, as the proposed regulations come into play if the licensee is to be disciplined for unprofessional conduct involving the use of drugs, alcohol, or another prohibited substance, and occurs after a full administrative hearing or upon stipulation. The emergency cease-practice orders required by these regulations, such as when a licensee tests positive for a prohibited substance while on probation, are necessary for public protection, and also have a time limitation for the Board to confirm results. Finally, a licensee continues to have the right to file a writ with a Superior Court for review of the Board's decision.

8. <u>Comments by Julianne D'Angelo Fellmeth, Administrative Director for the Center</u> <u>for Public Interest Law (Ms. Fellmeth's written comments were reiterated, in part,</u> <u>at the hearing)</u>

Comment 8.1 – Ms. D'Angelo Fellmeth pointed out that some language was missing under 1361.5(c)(5) that is provided for under Uniform Standard #4, namely: "Thereafter [i.e., after the second year of probation (sic)], administration of one (1) time per month if there have been no positive drug tests in the previous five (5) consecutive years of probation or diversion. Nothing precludes a board from increasing the number of random tests for any reason. Any board who finds or has suspicion that a licensee has committed a violation of the board's testing program or who has committed a Major violation, as identified in Uniform Standard 10, may reestablish the testing cycle by placing that licensee at the beginning of level 1, in addition to any other disciplinary action that may be pursued."

Proposed Response 8.1 – Staff recommends accepting this comment, in part, and has amended the language now under 1361.5(c)(3), regarding biological fluid testing to include the testing schedule provided for under Uniform Standard #4, and to clarify that the Board may increase the number of random tests for any reason. Further, under section 1361.52 of the new rewrite, the proposed language indicates that if the licensee has committed a major violation, the Board will take action, and may, among other things, increase the frequency of biological fluid testing, and refer the licensee for further disciplinary action.

Comment 8.2 – Ms. D'Angelo Fellmeth commented that some of the exceptions to the testing frequency schedule Uniform Standard #4 were not included in the proposed regulation, specifically regarding previous testing/sobriety, violations outside of employment, tolling, and testing for licensees not employed in a healthcare field. She stated that these provisions should be included.

Proposed Response 8.2 – Staff recommends accepting this comment, and has amended the language to include all of the exceptions to the testing frequency schedule under 1361.5(c)(3)(I).

Comment 8.3 – Ms. D'Angelo Fellmeth commented that several sections toward the end of Uniform Standard #4, namely "Petitions for Reinstatement," "Outcomes and Amendments," "Historical Data – Two Years Prior to Implementation of Standard," "Post Implementation Data – Three Years," and "Data Collection" were not included in the draft regulation, but should be.

Proposed Response 8.3 – Staff recommends accepting this comment and has amended the language to include all of these provisions from Uniform Standard #4. The section on Petitions for Reinstatement is included under 1361.5(c)(3)(J), and the reporting requirements have been placed in a separate proposed section, 1361.55(e).

Comment 8.4 – Ms. D'Angelo Fellmeth commented that 1361.5(c)(4) relating to group support meetings authorizes the Board to order a licensee to go to group meetings following such recommendation by the evaluator, however Uniform Standard #5 does not contain that limitation. She says that a board may order a licensee to attend group meetings even if that has not been recommended by an evaluator, and that the limitation should be removed.

Proposed Response 8.4 – Staff recommends accepting this comment, and has amended the language to read, "If the Board requires a licensee to participate in group support meetings, the following shall apply:..."

Comment 8.5 – Ms. D'Angelo Fellmeth commented that provisions under Uniform Standard #6 used in determining whether inpatient/outpatient or other type of treatment is necessary were not included in the draft regulations, but should be.

Proposed Response 8.5 – Staff recommends accepting this comment, in part, and has amended the language to include the provisions under 1361.5(c)(1)(A)(v) to be factored into the clinical evaluator's recommendations. The Board will not be ordering licensees into a specific type of program, but the clinical evaluator will make treatment recommendations based on the provisions of Uniform Standard #6.

Comment 8.6 – Ms. D'Angelo Fellmeth pointed out there is a discrepancy between the provisions of Uniform Standard #7 and the draft regulation under 1361.5(c)(3) with regard to how and when a worksite monitor reports suspected substance abuse.

Proposed Response 8.6 – Staff recommends accepting this comment, and has made a proposed amendment to the language under 1361.5(c)(5)(C)(i) to read as follows:

The worksite monitor shall verbally report any suspected substance abuse to the Board and the licensee's employer or supervisor as defined in subsection

(c)(2) within one (1) business day of occurrence. If the suspected substance abuse does not occur during the Board's normal business hours, the verbal report shall be made to the Board within one (1) hour of the next business day. A written report that includes the date, time, and location of the suspected abuse, the licensee's actions and any other information deemed important by the worksite monitor shall be submitted to the Board within 48 hours, or by the next business day, of the occurrence.

Comment 8.7 – Ms. D'Angelo Fellmeth stated that the draft regulations did not include all of the provisions of Uniform Standard #10 regarding major violations, and specifically did not include "failure to complete a board-ordered program" as a major violation. She proposed that since the Board may determine that the phrase is referring to a diversion program, which the Board no longer has, then the Board should consider including the failure to complete the probationary terms and conditions as a major violation.

Proposed Response 8.7 – Staff recommends accepting this comment, in part. The Board will not order the licensee into any particular treatment program. Staff, however, has amended the language under 1361.52(a)(8) to include the failure "to comply with any term or condition of his or her probation that impairs public safety," as a major violation. The limitation that it has to impair public safety is an important distinction from what qualifies as a minor violation.

Comment 8.8 – Ms. D'Angelo Fellmeth stated that the consequences for a major violation under Uniform Standard #10 are not discretionary, but the draft regulation has made implementation of the consequences discretionary by the use of "may." She contended that if a licensee commits a major violation, the Board is required to issue a cease practice order, and order the licensee to undergo a new clinical diagnostic evaluation, and require the licensee to test negative for at least a month of continuous testing before being allowed to go back to work.

Proposed Response 8.8 – Staff recommends accepting this comment, in part, and has amended the language under 1361.52(b) to include the following language: **"If a licensee commits a major violation, the Board will take one or more of the following actions:..."**

While staff agrees that action is required when a licensee commits a major violation, the Board retains discretion on what consequences to impose. Not all major violations are created equal. For example, committing multiple minor violations, which may include missing group support meetings, is considered a major violation along with treating patients while under the influence of a prohibited substance. A cease practice order and referral for revocation may not be warranted under the first example, but would be warranted under the second.

Comment 8.9 – Ms. D'Angelo Fellmeth stated that Uniform Standard #10 contains seven consequences that appear to be mandatory, but the proposed regulation only includes three of those seven, and does not make the consequences mandatory.

Proposed Response 8.9 – Staff recommends accepting this comment, in part, and has amended the language under 1361.52(c) to include the seven consequences contained in Uniform Standard #10 for a minor violation. Additionally, the language has been amended to state: **"If a licensee commits a minor violation, the Board will take one or more of the following actions:..."**

Staff disagrees that all of the consequences for a minor violation are mandatory, and the Board retains discretion on what consequences to impose.

Comment 8.10 – Ms. D'Angelo Fellmeth stated that the Board should include Uniform Standard #12, regarding an informal petition for reinstatement, in its proposed regulation.

Proposed Response 8.10 – Staff recommends rejecting this comment. The Board does not have a mechanism for considering informal petitions for reinstatement. An individual whose license has been revoked can petition for reinstatement under Government Code section 11522, and will be required to show clear and convincing evidence of rehabilitation. These petitions are decided by an administrative law judge and are subject to Board approval.

Comment 8.11 – Ms. D'Angelo Fellmeth pointed out that the proposed regulation does not contain Uniform Standards #13, #14, and #15, which contain standards pertaining to boards that contract with an outside vendor to operate a diversion program. While she acknowledged that the Board does not contract with vendors to operate a diversion program, she stated that Uniform Standard #13 contains some important standards for specimen collectors, and she encouraged the Board to include those standards.

Proposed Response 8.11 – Staff recommends accepting the comment to the extent it asks that the standards for specimen collectors be included. Staff has drafted a new section, 1361.54 - Requirements for Laboratories/Testing Locations and Specimen Collectors for Testing Substance-Abusing Licensees, and has included the requirements from Uniform Standard #4 and #13, dealing with laboratories/testing locations and specimen collectors.

Because Uniform Standards #14 and #15 deal with private-sector vendors not used by the Board, staff has determined that they should not be included in these regulations. At a later point, if the Board amends the disciplinary guidelines to include monitoring by a vendor, then, at that same time, the Board would have to adopt the Uniform Standards dealing with vendors.

Comment 8.12 – Ms. D'Angelo Fellmeth states that Uniform Standard #16, which addresses mandatory reporting by the Board to DCA and the Legislature regarding a number of factors relating to substance-abusing licensees, is not included in the proposed regulation, and should be.

Proposed Response 8.12 – Staff recommends accepting this comment, and has drafted a new section, 1361.55 – Reporting Requirements Relating to Substance-Abusing Licensees, that is consistent with Uniform Standard #16.

9. <u>Comments by Michelle Monserrat Ramos, Consumers Union, California Safe Patient</u> <u>Network Made at the October 25, 2013 Hearing</u>

Comment 9.1 – Ms. Monserrat Ramos asked that the Board implement the full Uniform Standards as SB 1441 requires. She says she cannot believe how long it is taking to implement the Uniform Standards. She wants to remind the Board that patients have died due to substance-abusing physicians. She reiterated the written comments received from Consumers Union regarding provisions not included in the draft regulation.

Proposed Response 9.1 – Staff recommends accepting this comment, in part. Staff has made substantial changes to the proposed regulation in the rewrite so that the language is more consistent with SB 1441 where appropriate. Moreover, the reporting requirements from Uniform Standards #4 and #16 are now included in a separate regulatory section, 1361.55, as a directive to the Board.

Staff recommends rejecting this comment to the extent that it calls for the inclusion of all provisions of the Uniform Standards in the proposed regulations. There are some Uniform Standards that staff deems are not appropriate for the Board to include at this time. For example, most of Uniform Standards #13, and #14 and #15, dealing with private-sector vendors not used by the Board, should not be included. If the Board amends the disciplinary guidelines to include monitoring by a vendor in the future, then, at that same time, the Board would have to adopt the Uniform Standards dealing with vendors.