

TITLE 16. PHYSICIAN ASSISTANT BOARD

NOTICE IS HEREBY GIVEN that the Physician Assistant Board is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at 2005 Evergreen Street, Hearing Room Sacramento, California, at 9:00 a.m., on 9 February 2015. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Physician Assistant Board at its office not later than 5:00 p.m. on 9 February 2015 or must be received by the Physician Assistant Board at the hearing. The Physician Assistant Board, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Sections 3510, 3527, 3528, 3529, 3530, 3531, 3532, and 3533 of the Business and Professions Code, and Section 11400.20 of the Government Code and to implement, interpret or make specific Sections 11400.20 and 11425.50(e) of the Government Code and 315, 315.2, 315.4, 729, 3527, 3528, 3529, 3530, 3531, and 3533 of the Business and Professions Code, the Physician Assistant Board is considering changes to Division 13.8 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST

A. Informative Digest

Business and Professions Code Section 3510 authorizes the Board to adopt, amend, or repeal regulations as may be necessary to enable it to carry into effect the provisions of the Physician Assistant Practice Act.

Existing law, Business and Professions Code Section 315, established the Substance Abuse Coordination Committee (SACC) within the Department of Consumer Affairs (Department) and required the SACC to formulate uniform and specific standards in sixteen specified areas for each healing arts boards to use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program.

Business and Professions Code Section 315.2 specifies that a healing arts board within the Department is required to order a licensee to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program. The cease practice order pursuant to this section does not constitute disciplinary action and is not subject to adjudicative hearings.

Business and Professions Code section 315.4 authorizes healing arts boards within the Department to order a licensee on probation or in a diversion program to cease practice for major violations and when the board orders a licensee to undergo a clinical diagnostic evaluation pursuant to the uniform and specific standards adopted and authorized under section 315. The cease practice order pursuant to this section does not constitute disciplinary action and is not subject to adjudicative hearings.

Title 16, California Code of Regulations Section 1399.523 incorporates by reference the "Physician Assistant Board Manual of Model Disciplinary Guidelines and Model Disciplinary Orders, (hereinafter referred to as the "Guidelines,") 3rd Edition, 2007.

The Guidelines are intended as a guide to persons involved in setting administrative disciplinary terms and conditions for violation by licensed physician assistants of the Physician Assistant Practice Act and other laws and regulations applicable to physician assistants and the practice of medicine. The use of the Guidelines helps to ensure that the selected terms and conditions are appropriate and consistent with decisions reached in comparable disciplinary actions for physician assistants.

This proposal will amend Section 1399.523 to incorporate by reference the 4th Edition Guidelines as proposed by the Board in August 2013, which includes provisions that would implement the Uniform Standards formulated by the SACC pursuant to Section 315. As part of that implementation, this proposal would also add a new provision to Section 1399.523 that would specify that a clinical diagnostic evaluation shall be ordered in every probationary case where the conduct found to be a violation involves drugs, alcohol, or both.

Additionally, this proposal will further amend Section 1399.523 to incorporate by reference the SACC's April 2011 document entitled "Uniform Standards Regarding Substance-Abusing Healing Arts Licensees" (hereinafter referred to as the "Uniform Standards"). This proposal would adopt these uniform standards established by the SACC and also standard language ("Conditions Applying the Uniform Standards") for probationary orders to be used by Administrative Law Judges, Deputy Attorneys General and the Board if a licensee is determined to be a substance abuser. This proposal would also specify that the proposed provisions contained in section 1399.523 would not prohibit the Board from imposing additional terms or conditions of probation that would provide greater public protection.

In addition to proposing to adopt the Uniform Standards formulated by the SACC, the Board is also proposing the following updates to the Guidelines:

1. Senate Bill 1236 (Chapter 332, Statutes of 2012) changed the name of the Physician Assistant Committee to Physician Assistant Board, effective January 1, 2013. The Guidelines are being modified to reflect the name change throughout the document.
2. The Introduction would be modified to reference the use of the Uniform Standards and their application to probationary orders in light of the Board's public protection mandate. In addition, the Introduction would add "Special Circumstances" applicable to certain disciplinary cases involving sexual contact

sexual offenses, drugs, alcohol or violations involving the Medical Practice Act. Section 1399.523 is also re-stated here for ease-of-reference.

3. An explanation of the distinctions between self-referrals and probationary participants and an overview of participant requirements and costs for the Board's alcohol and drug recovery monitoring program would be included at the beginning of the Guidelines.
4. In the "Causes for Discipline and License Restriction": Sections 726, 729, and 3527(a) - Sexual Misconduct violations section is being amended to add language from existing Title 16, CCR sections 1399.523 and 1399.523.5 regarding required penalties (revocation/denial) for sexual misconduct if the individual is required to register as a sex offender. Additional terms and conditions of probation would also be added for this type of violation if probation is imposed and drugs or alcohol violations are present, consistent with the Uniform Standards.
5. In the "Causes for Discipline and License Restriction" portion of the Manual, the following sections will be amended to reference consideration of the Uniform Standards in imposing discipline, including the ability to make the standards contingent upon a clinical diagnostic evaluator's finding that the individual is a substance abuser:
 - §820 – Mental or Physical Illness;
 - §2237 & §3527(a) Conviction Related to Drugs;
 - §2239 & §3527(a) Drug or Alcohol Abuse
 - §2241 & §3527(a) Furnishing Drugs or Transmitting Drug Orders to Addict;
 - §2242 & 3527(a) Administering or Furnishing Drugs, or Transmitting Drugs Orders, Without Prior Good Faith Examination; and,
 - §3527(a) Administering, Furnishing, or Transmitting Drug Orders Not Prescribed by Supervising Physician;

Additional terms and conditions of probation would also be added for these types of violations if probation is imposed and drug or alcohol violations are present, consistent with the Uniform Standards.

6. In the "Causes for Discipline and License Restriction" portion of the Manual, the following violation sections will be amended to require consideration of a prescribing practices course (as described in the Optional Conditions): excessive treatments, sexual misconduct, gross negligence, repeated negligent acts, incompetence, dishonesty, conviction related to drugs, violation of drug statutes, drug or alcohol abuse, intoxication while treating patients, furnishing drugs or transmitting drug orders to addict, administering or furnishing drugs, or transmitting drugs orders, without prior good faith examination, illegal cancer treatment, making or signing false documents, alteration of medical records, administering, furnishing, or transmitting drug orders not prescribed by supervising physician, practicing medicine without delegated authority from a supervising physician, operating delegated areas of practice and practicing

without adequate supervision.

7. Model Order 3, "Initial Probationary License" "Notes" section is being modified to add clarification language where a license is being issued, the condition deadlines should commence from the issuance of the license rather than issuance of the decision.
8. Optional Condition 7, "Controlled Drugs – Maintain Record" is being modified to require that controlled substances records must remain at the worksite and be available for inspection by the Board or its designee at all times during business hours.
9. The current Optional Conditions related to abstention from drugs or alcohol, biological fluid testing, and diversion are being modified and moved to a new section entitled "Conditions Applying the Uniform Standards."
10. Optional Condition 11 "Clinical Training Program" is being modified to include language to clarify the consequences for failure to complete or pass the clinical training program and an Option 2 that requires completion of the clinical training program prior to the issuance of a license (Condition Precedent).
11. Optional Condition 14 "Prescribing Practices Course" has been added. This condition would require the probationer to enroll in a course equivalent to the Prescribing Practices Course at the Physician Assessment and Clinical Education Program, University of California, San Diego School of Medicine within 60 days of the effective date of the Board's decision.
12. Optional Condition 17, "Third Party Chaperone" is being modified to add clarification language that all required logs must remain at the worksite and be available for inspection by the Board or its designee.
13. Optional Condition 19 "Maintenance of Patient Medical Records" "Option 1" is being modified to require that written medical records must remain at the worksite and be available for immediate inspection by the Board or its designee on the premises at all times during business hours.
14. A new section is being added entitled "Conditions Applying Uniform Standards Related to Substance Abuse", which includes probationary terms that must be used in all cases when the violation involved the licensee's use of drugs, alcohol, or both. Those terms and conditions are:
 - a) Clinical Diagnostic Evaluation: This condition of probation requires the probationer to undergo a clinical diagnostic evaluation as specified.
 - b) Abstain from Use of Alcohol, Controlled Substances, and Dangerous Drugs: These conditions of probation require the probationer to abstain completely from the use of alcohol, controlled substances, and dangerous drugs unless lawfully prescribed as specified.

c) Drug and Alcohol Recovery Program: This condition of probation requires the probationer to enroll in and successfully complete the Board's drug and alcohol recovery monitoring program. The probationer is responsible for all costs associated with the program.

d) Biological Fluid Testing: This condition of probation requires the probationer to comply with specified drug and alcohol testing requirements. The probationer is responsible for all costs associated with testing.

e) Facilitated Group Support Meetings: This condition of probation requires the probationer to attend facilitated group support meetings as specified.

f) Work Site Monitor: This condition of probation requires the probationer to comply with specified work site monitor requirements.

g) Major Violations: This condition of probation requires the probationer to immediately cease practice upon notification by the Board that the he or she has committed a major violation, as specified.

15. Optional Condition 29 "Approval of Supervising Physician" is being modified to require that if the supervising physician resigns or is no longer available, within 15 days the respondent shall notify the Board of a new supervising physician and respondent may not practice until a new supervising physician has been approved by the Board or its designee.
16. Optional Condition 30 "Notification of Employer and Supervising Physician" is being updated to require respondent to provide a copy of the accusation, decision, and order before accepting or continuing employment. The condition shall also apply to any changes in place of employment. Additional language is included to state that the respondent shall provide practice site information, contact information, and shall give written consent to allow Board staff to communicate with respondent's employer, supervising physician, or work site monitor regarding their work status, performance, and monitoring.
17. Optional Condition 35 "Non-practice While on Probation," is being added replacing "Tolling for Out-of-State Practice or Residence" and "Failure to Practice as a Physician Assistant – California Resident" combining the language of the two tolling/non practice conditions (out of state and in state) into one condition of non-practice for a probationer.

B. Policy Statement Overview/Anticipated Benefits of Proposal

The Uniform Standards are being adopted into regulation by Department of Consumer Affairs healing arts boards, including the Physician Assistant Board, to ensure that consumer safety remains their paramount mission and to implement consistent practices with regard to substance-abusing licensees.

The Board's Guidelines were established to facilitate uniformity in taking appropriate disciplinary action against licensees and to provide transparency in

regards to the Board's actions when imposing discipline.

The Uniform Standards not only address penalties for licensees, but administrative requirements for the Board, and, if applicable, the monitoring program. The Board will use the amended provisions of Section 1399.523 and the Guidelines when taking action to suspend, revoke, or place a license on probation when the individual has been determined to be a substance abuser. Updating the Guidelines will ensure continued consumer protection through consistent application and interpretation of the standards and increased monitoring of substance abusing licensees. The proposed language is necessary to aid the Board in the discipline and monitoring of substance abusing licensees to provide better public protection to the people of California.

C. Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the Physician Assistant Board has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

INCORPORATION BY REFERENCE

1. Physician Assistant Board Manual of Disciplinary Guidelines and Model Disciplinary Orders, 4th Edition, 2014.
2. Department of Consumer Affairs' Substance Abuse Coordination Committee's document entitled "Uniform Standards Regarding Substance-Abusing Healing Arts Licensees" (April 2011).

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Sections 17500 - 17630 Require Reimbursement: None.

Business Impact:

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states because it will only impact physician assistant licensees subject to disciplinary action. The Board only has authority to take administrative action against a licensee and not a business. Accordingly, the initial or ongoing impact to a business at which a licensee works who is the

subject of disciplinary action cannot be projected. Businesses employing licensees who are in compliance with the law will not incur any fiscal impact.

The following studies/relevant data were relied upon in making the above determination:

The Board currently regulates approximately 9,000 physician assistants. Any "adverse economic impact" would only occur as the result of a disciplinary order following a formal administrative proceeding and a finding of fact affirming a violation of the Board's laws or regulations and would only affect individuals who are disciplined by the Board. Any potential "adverse economic impact" may be avoided simply by complying with the law. Licensees who are placed on probation as a result of a violation involving drugs or alcohol and are deemed to be substance-abusing may incur additional costs as set forth in the "Cost Impact on Representative Private Person or Business" section below.

Cost Impact on Representative Private Person or Business:

The Board identified potentially significant costs which only impact those licensees who have been deemed substance-abusing and are subject to the Uniform Standards. The Uniform Standards are part of the monitoring program in which substance-abusing licensees are required to participate, pursuant to their terms of probation. The monitoring program with which the Board contracts with has already implemented the Uniform Standards.

The following costs may be incurred by licensees participating in the Board's monitoring program:

1. Monthly participation fee: \$306. The monthly participation fee increase 3 to 5 % annually.
2. Biological Fluid Testing: the average cost for each test is approximately \$60.00 per test plus a collection fee at the testing site which can cost up to \$125.
3. Professional Support Group Meetings: \$200 to \$500 monthly.
4. Inpatient Treatment Program may be required: \$3,000 to \$5,000.
5. Clinical Diagnostic Evaluation: \$2,000 to \$5,000 per evaluation.

EFFECT ON HOUSING COSTS: None

EFFECT ON SMALL BUSINESS

The Physician Assistant Board has determined that the proposed regulations would not affect small businesses. The proposed regulation will only affect individual licensees. The Board only has authority to take administrative action against a licensee and not a business. Accordingly, the initial or ongoing costs for a small business at which a licensee works who is the subject of disciplinary action cannot be projected. Businesses employing licensees who are in compliance with the law will not incur any fiscal impact.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/Businesses:

The Physician Assistant Board has determined that this regulatory proposal will not have any significant impact on the creation of jobs or new businesses or the expansion of businesses in the State of California because it will only impact licensees subject to disciplinary action. The Board only has authority to take administrative action against a licensee and not a business. Accordingly, the initial or ongoing costs for a small business at which a licensee works who is the subject of disciplinary action cannot be projected. Businesses employing licensees who are in compliance with the law will not incur any fiscal impact

It will not eliminate jobs within the State of California because the proposal imposes specific requirements on a specific set of licensees who are subject to disciplinary action due to violations of the law and may be subject to more rigorous Uniform Standards due to violations of law involving drugs or alcohol. A business owned by a licensee who faces disciplinary action may incur a significant fiscal impact depending on the nature and severity of the violation.

The Board does not maintain data relating to the number or percentage of licensees who own a business; therefore, the number or percentage of businesses that may be impacted cannot be predicted. The Board only has authority to take administrative action against a licensee and not a business.

Accordingly, the initial or ongoing costs for a small business owned by a licensee who is the subject of disciplinary action cannot be projected. Businesses operated by licensees who are in compliance with the law will not incur any fiscal impact.

Benefits of Regulation:

The Board has determined that this proposed regulatory change updating the Board's Guidelines will benefit California consumers by enhancing the Board's ability discipline physician assistants who violate the Physician Assistant Practice Act or other laws and regulations regarding the practice of medicine by a physician assistant. In addition, incorporating the Uniform Standards provides maximum protection to California consumers against licensees who are found to be in violation of the law or who do not demonstrate the competency necessary to perform their duties due to substance abuse. These benefits are a direct result of the Board's statutorily mandated priority set forth in Business and Professions Code section 3504.1. The protection of the public is the highest priority for the Board in exercising licensing, regulatory, and disciplinary functions. The proposed adoption of these additional probation conditions will ensure that individuals who have been determined to be substance-abusing licensees will be effectively disciplined in a manner that will protect the public. Additionally, updated Guidelines will provide clarity for licensees to understand what

Judges and Attorney Generals will also benefit from the updated Guidelines when drafting decisions, which will help ensure consistency in interpretation and application of penalties in disciplinary matters.

CONSIDERATION OF ALTERNATIVES

The Physician Assistant Board must determine that no reasonable alternative is considered to the regulation or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Physician Assistant Board has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the Physician Assistant Board at 2005 Evergreen Street, Suite 1100, Sacramento, California 95615.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the Physician Assistant Board's website below.

CONTACT PERSON

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

Name: Glenn L. Mitchell, Jr.
Address: 2005 Evergreen Street, Suite 1100
Sacramento, CA 95815
916 561-8783

Fax No.: 916.263.2671
E-Mail Address: glenn.mitchell@mbc.ca.gov

The backup contact person is:

Name: Lynn Forsyth
Address: 2005 Evergreen Street, Suite 1100
Sacramento, CA 95815
Telephone No.: 916.561-8785
Fax No.: 916.263.2671
E-Mail Address: lynn.forsyth@mbc.ca.gov

Website Access: Materials regarding this proposal can be found at: www.pac.ca.gov.