

TITLE 16. PHYSICIAN ASSISTANT BOARD

NOTICE OF PROPOSED RULEMAKING CONCERNING SB 697 IMPLEMENTATION

(Notice Published July 28, 2023)

The Physician Assistant Board (Board) proposes to adopt the proposed regulations described below after considering all comments, objections, and recommendations regarding the proposed action.

PUBLIC HEARING

The Board has not scheduled a public hearing on this proposed action. However, the Board will hold a hearing if it receives a written request, addressed to the individuals listed under “Contact Person” in this notice, for a public hearing from any interested person, or their authorized representative, no later than 15 days prior to the close of the written comment period.

WRITTEN COMMENT PERIOD

Any interested person, or their authorized representative, may submit written comments relevant to the proposed regulatory action to the Board. Comments may also be submitted by mail, facsimile (FAX), or e-mail to the addresses listed under “Contact Persons” in this Notice. The written comment period closes at **5:00 p.m. on Tuesday, September 12, 2023**. The Board will consider only comments received at the Board’s office by that time, or comments received at the hearing if the Board holds a hearing.

AUTHORITY AND REFERENCE

Business and Professions Code (BPC) section 3510 authorizes the Board to adopt this proposed regulation. The proposed regulation implements, interprets, and makes specific the provisions of Senate Bill 697 (Caballero, Chapter 707, Statutes of 2019), and the Board is seeking to amend section 1399.502 of Article 1 and sections 1399.540, 1399.541, and 1399.545 of Article 4 of Division 13.8 of Title 16 of the California Code of Regulations (CCR).

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Board licenses, regulates, and investigates complaints against licensed physician assistants (PAs) in California, totaling approximately 16,378 licensees. It is the Board’s duty to enforce and administer the Physician Assistant Practice Act (Chapter 7.7 (commencing with section 3500) of Division 2 of the BPC) (Practice Act). The Board is authorized to establish necessary rules and regulations for the enforcement of the Practice Act and the laws subject to its jurisdiction (BPC section 3510).

Senate Bill (SB) 697 (Caballero, Chapter 707, Statutes of 2019) became effective on January 1, 2020 and made numerous changes to the Practice Act, which provides for licensure and regulation of PAs by the Board. Generally, the changes remove requirements that the medical record identify the responsible supervising physician and

surgeon (physician), remove requirements that the physician be physically available to the PA for consultation, remove requirements for review and countersignature of patient medical records, and remove requirements that written guidelines for adequate supervision be established. The law now authorizes a PA to perform medical services authorized by the Practice Act if certain requirements are met, including that the medical services are rendered pursuant to a practice agreement, as defined, and the PA is competent to perform the medical services.

Certain Board regulations that were based on the Practice Act before the changes made by SB 697 now conflict with the law. The Practice Act now requires that a practice agreement between a PA and a physician meet specified requirements, such as that a practice agreement must contain policies and procedures to ensure adequate supervision of the PA, which should cover appropriate communication, availability, consultations, and referrals between a physician and the PA in the provision of services. In addition, a practice agreement must establish policies and procedures to identify the physician who is supervising a PA rendering services in a general acute care hospital.

The prior law authorized a PA to administer or provide medication to a patient and transmit orally or in writing on a patient's record or in a drug order, an order to a person who may lawfully furnish the medication or medical device, under the supervision of a physician, subject to specified requirements. The law now authorizes a PA to furnish or order a drug or device without the supervision of a physician, subject to specified requirements, such as the PA's educational preparation, that clinical competency has been established and maintained, and that the physician shall be available by telephone or other electronic communication method at the time the PA examines the patient. The changes made to the Practice Act now authorize a PA to furnish or order Schedule II or III controlled substances in accordance with the practice agreement or a patient-specific order approved by the treating or supervising physician. The revisions to the Practice Act require completion of a controlled substances course by or before the PA's next license renewal, if the PA is authorized by a practice agreement to furnish Schedule II controlled substances and if the PA has a United States Drug Enforcement Administration registration.

In addition, the new law provides that any reference to a "delegation of services agreement" in any other law now means "practice agreement" as defined. The Practice Act now provides that supervision does not require the supervising physician to be physically present but requires adequate supervision as agreed to in the practice agreement and requires that the physician be available by telephone or other electronic communication method at the time a PA examines a patient. However, the Practice Act prohibits that requirement from being construed as prohibiting the Board from requiring the physical presence of a physician as a term or condition of a PA's reinstatement, probation, or the imposition of discipline.

Anticipated Benefits of the Proposed Regulation:

The four regulation sections that are the subject of this proposed regulatory action now conflict with the law since the passage of SB 697. The proposed amendments bring these four regulation sections up-to-date and into compliance with SB 697. This is accomplished by amending 16 CCR section 1399.502 to clarify that any reference to a "delegation of services agreement" in any other section of the PA regulations means "practice agreement," as defined in BPC section 3501(k). The amendments also clarify the reference to "supervision" as defined in BPC section 3501(f), to include that supervision

does not require the supervising physician to be physically present but does require adequate supervision as agreed to in the practice agreement and does require that the physician be available by telephone or other electronic communication method at the time the PA examines the patient.

The proposed amendments to 16 CCR section 1399.540 make the section comply with SB 697 by updating any reference to the supervision agreement from “delegation of services agreement” to “practice agreement.” The amendments also bring the section into compliance with SB 697 by recognizing that a PA is authorized to practice and no longer delegated. The amendments further reflect the existing standard of care for physicians and further the legislative intent of SB 697 by recognizing that a PA may consult with or refer to a provider other than a physician when appropriate under the circumstances.

The proposed amendments to 16 CCR section 1399.541 make the section comply with SB 697 by deleting a reference to the word “agent,” as BPC section 3502.3 states that a practice agreement “may” designate a PA as an agent of the physician, but it is not required. The amendments further clarify that a supervising physician must be immediately available to the PA if needed, because the physical presence of the supervising physician during the time a PA is delivering medical services is not required.

The proposed amendments to 16 CCR section 1399.545 remove existing regulatory requirements that conflict with SB 697 and amend the remaining requirements to conform with the changes. The amendments reflect the removal of the required written guidelines including countersignature and dating of all medical records written by the PA, pursuant to BPC section 3502(c). The amendments also replace the term “autonomously” with the phrase “without supervision” to better capture the scope of PA practice.

Evaluation of Inconsistency/Incompatibility with Existing State Regulations:

During the process of developing these regulations and amendments, the 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.

DISCLOSURES REGARDING THE PROPOSED ACTION

FISCAL IMPACT ESTIMATES

The proposed regulations do not result in a fiscal impact to the state because the amendments align the Board’s regulations with current law and/or with existing practice.

The proposed regulations do not result in a fiscal impact to the state in the form of federal funding or any cost or savings to any state agency.

The Board has made the following initial determinations:

Mandate on local agencies and school districts: None.

Cost or savings to any state agency: None. The regulations do not result in a fiscal impact to the state. The amendments align the Board's regulations with current law and existing practice.

Cost to any local agency or school district for which Government Code sections 17500 through 17630 requires reimbursement: None.

Other nondiscretionary cost or savings imposed on local agencies: None.

Cost or savings in federal funding to the state: None. There are no costs or savings in federal funding to the state.

Cost impacts on a representative private person or business: The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Significant effect on housing costs: None.

Business Impact:

The Board has determined that the proposed regulation will not have any significant statewide adverse economic impact directly affecting businesses, including the ability to compete.

Effect on Small Business:

The Board has determined that the proposed regulation would not affect small businesses because the proposal only replaces any reference to "delegation of services agreement" with "practice agreement," removes repeated terms already defined in statute, clarifies the standard of care and legislative intent of SB 697 by recognizing that a PA may consult with or refer to a provider other than a physician where appropriate under the circumstances and removes other existing regulatory requirements that conflict with SB 697.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS

This regulatory proposal will have the following effects:

It will not create or eliminate jobs within the state of California because the proposal only replaces any reference to "delegation of services agreement" with "practice agreement," removes repeated terms already defined in statute, clarifies the standard of care and legislative intent of SB 697 by recognizing that a PA may consult with or refer to a provider other than a physician where appropriate under the circumstances and removes other existing regulatory requirements that conflict with SB 697.

It will not create new businesses or eliminate existing businesses within the state of California because the proposal only replaces any reference to "delegation of services agreement" with "practice agreement," removes repeated terms already defined in statute, clarifies the standard of care and legislative intent of SB 697 by recognizing that

a PA may consult with or refer to a provider other than a physician where appropriate under the circumstances and removes other existing regulatory requirements that conflict with SB 697.

It will not affect the expansion of businesses currently doing business within the state of California because the proposal only replaces any reference to “delegation of services agreement” with “practice agreement,” removes repeated terms already defined in statute without justification for the duplication, clarifies the standard of care and legislative intent of SB 697 by recognizing that a PA may consult with or refer to a provider other than a physician where appropriate under the circumstances and removes other existing regulatory requirements that conflict with SB 697.

It will benefit the health and welfare of California residents to align the Board’s regulations with the changes to statute resulting from the passage of SB 697. By adopting this regulation, the Board seeks to support PAs who serve an increasingly diverse public, and to uphold the Board’s highest priority, which is to protect consumers.

This regulatory proposal will not affect worker safety or the state’s environment because aligning the Board’s regulations with the statutory changes caused by the passage of SB 697 does not impact worker safety or involve the state’s environment.

CONSIDERATION OF ALTERNATIVES

The Board must determine that no reasonable alternative to the regulatory proposal that was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective or less burdensome to affected private persons than the proposed regulation, or would be more cost-effective to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. All recommendations provided during the rulemaking process will be considered by the Board.

The Board invites interested persons to present statements or arguments with respect to alternatives to the proposed regulation at any scheduled hearing or during the written comment period.

CONTACT PERSONS

Inquiries concerning the proposed administrative action may be directed to:

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AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS AND RULEMAKING FILE

The Board will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the above address. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulation, the initial statement of reasons, and other information on which the rulemaking is based.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments received, the Board, upon its own motion or at the request of any interested party, may adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations if such modifications are sufficiently related to the originally proposed text. With the exception of technical or grammatical changes, the full modified text (with the changes clearly indicated) will be available to the public for review and written comment on the modifications for at least 15 days prior to its adoption. Please send requests for copies of any modifications to the proposed regulations to the attention of the Contact Person designated at the address indicated above. Modifications will also be mailed to those persons who submit written comments or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

Upon its completion, copies of the Final Statement of Reasons may be obtained by contacting the Contact Person at the above address.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulation with additions in underline and deletions in strikethrough can be accessed through our website at: <https://pab.ca.gov/lawsregs/regulations.shtml>.