

**TITLE 16. PHYSICIAN ASSISTANT BOARD
DEPARTMENT OF CONSUMER AFFAIRS**

INITIAL STATEMENT OF REASONS

SB 697 Implementation

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

Subject Matter of Proposed Regulations: SB 697 Implementation

Sections Affected: Amend Article 1, Section 1399.502, and Article 4, Sections 1399.540, 1399.541, and 1399.545 of Division 13.8 of Title 16 of the California Code of Regulations¹ (CCR).

Background and Statement of the Problem:

The Physician Assistant Board (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 Business and Professions Code (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.

¹ All references are to 16 CCR unless otherwise noted.

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 from this regulatory action:

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.

Specific Purpose of, and Rationale for, Each Amendment:

SB 697 made numerous changes to PA practice. At the August 7, 2020, Board meeting, the Board discussed and voted to amend CCR sections 1399.502, 1399.540, 1399.541, and 1399.545. On July 23, 2021, the California Academy of PAs (CAPA) sent the Board a letter raising concerns about the proposed changes and another proposed regulation package also implementing SB 697 changes. On October 13, 2021, Board President Juan Armenta, Board Vice President and PA Sonya Early, Executive Officer Rozana Khan, Analyst Jasmine Dhillon, Staff Services Manager Kirsty Voong, Board Counsel Michael Kanotz, and Regulations Counsel Karen Halbo met with representatives from CAPA to discuss CAPA’s concerns. Revised regulatory text was drafted for the Board’s consideration. At the Board’s November 8, 2021 meeting, the Board discussed and approved revisions to the previously approved changes to CCR sections 1399.502, 1399.540, 1399.541, and 1399.545 to better implement the changes needed in those regulation sections as a result of the passage of SB 697.

CCR section 1399.502 – Definitions

CCR section 1399.502 – Former subdivisions (c) and (d)

Purpose: This proposal would repeal the existing language in former subdivision (c) that defines the term “Physician assistant,” and repeal the existing language in former subdivision (d) that defines the term “Trainee.”

Anticipated Benefits/Rationale: The term “physician assistant” is defined in BPC section 3501(d). The term “Trainee” is defined in BPC section 3501(c). The removal of the language in former subdivisions (c) and (d) removes duplicative definitions and will increase clarity.

CCR section 1399.502 – Former subdivision (e), now subdivision (c)

Purpose: This proposal would move former subdivision (e) up to become subdivision (c) and capitalize the word “Board.”

Anticipated Benefits/Rationale: This proposal makes nonsubstantive changes for easier comprehension and readability of the regulation. In CCR section 1399.502(a) the capitalized word “Board” is defined to mean the Physician Assistant Board. Existing subdivision (e) would be renumbered to subdivision (c) to accommodate the deletion of former subdivisions (c), (d) and (e) and allow for greater comprehension and readability of the regulation.

CCR section 1399.502 – Former subdivision (f)

Purpose:

This proposal would repeal the existing language in subdivision (f) that defines the terms “Supervising physician” and “physician supervisor.”

Anticipated Benefits/Rationale: SB 697 added and defined the term “supervising physician” in BPC section 3501(e). The removal of this duplicative definition increases clarity. The term “physician supervisor” is not defined in BPC section 3501(e) and therefore the definition is removed here for clarity and to reduce confusion. This proposal will help reduce confusion regarding what the phrase “physician supervisor” might mean as it is not defined in the BPC. SB 697 established that a PA supervisor is to be referred to as “supervising physician” or “supervising physician and surgeon” as written in BPC section 3501(e).

CCR section 1399.502 – Former subdivision (g), now subdivision (d)

Purpose: This proposal would move former subdivision (g) up to become subdivision (d) and capitalize Board.

Anticipated Benefits/Rationale: This proposal makes nonsubstantive changes for easier comprehension and readability of the regulation. In CCR section 1399.502(a) the capitalized word “Board” is defined to mean the Physician Assistant Board. Existing subdivision (g) would be renumbered to be subdivision (d) to accommodate the deletion of former subdivisions (c), (d), (e), and (f) and allow for greater comprehension and readability of the regulation.

CCR section 1399.502 – New subdivision (e)

Purpose: This proposal would add a new subdivision (e) to provide a definition of “practice agreement” as set out in BPC section 3501(k) and require a practice agreement contain certain provisions that address the issues set out in BPC section 3502.3.

Anticipated Benefits/Rationale: SB 697 re-defined the term “practice agreement” in BPC section 3501(k) and set out required provisions that must be addressed in a practice agreement in BPC section 3502.3. The changes made by these two statutes are key to understanding the significant changes in PA practice made by the passage of SB 697. Pointing to where in statute “practice agreement” is defined, and the statutory requirements of a practice agreement within this regulation section that provides definitions for all PA regulation sections will increase clarity for PAs and the public.

CCR section 1399.502 – New subdivision (f)

Purpose: This proposal would add subdivision (f) to provide a definition of “supervision” as set out in BPC section 3501(f).

Anticipated Benefits/Rationale: SB 697 re-defined the term supervision in BPC section 3501(f). Pointing to where in statute “supervision” is now defined, within this regulation section that provides definitions for all PA regulation sections, will increase clarity for PAs and the public about the significant changes in PA practice created by the passage of SB 697.

Amend Section 1399.540 – Limitation on Medical Services

CCR Section 1399.540 – Subdivision (a)

Purpose: This proposal would remove the existing language in subdivision (a) and provide new language to clarify which medical services PAs are authorized to perform consistent with their practice agreements. This new language cites to BPC section 3502.3 regarding the Delegation of Services Agreement.

Anticipated Benefits/Rationale: The proposed language clarifies the requirements of a practice agreement by referring to BPC section 3502.3, which addresses the provisions required and issues that must be addressed in a practice agreement. The removal of the former language is required as it conflicted with the changes to PA practice after the passage of SB 697. The former language had contained a reference to services that are “delegated.” A PA’s legal authorization to practice is no longer delegated by a physician, it is authorized. SB 697 authorizes a PA to perform medical services authorized by the Practice Act if certain requirements are met, included that medical services are rendered pursuant to a practice agreement, as defined, and that the PA is competent to perform those medical services. The former language had also contained the word “only” in referring to medical services a PA could provide, which contradicts the SB 697 changes. Now the practice agreement also serves as an additional possible basis for a PA providing services. The use of the word “only” in the previous language created an incomplete and closed set of enumerated bases for PA practice.

CCR Section 1399.540 – Subdivision (b)

Purpose: This proposal would amend the existing language in subdivision (b) to clarify what is required for approval of a practice agreement. This proposal removes outdated language and replaces subdivision (b) with revised language that clarifies that a physician, a group of physicians, or a physician on the staff of an organized health care system can sign a practice agreement with a PA.

Anticipated Benefits/Rationale: The proposed language clarifies the requirements of a practice agreement and references BPC section 3502.3(a)(2)(B) regarding physicians on staff with an organized health care system. The proposed language removes the outdated phrase “delegation of services” which SB 697 replaced with “the practice agreement” as set out in BPC sections 3501(k) and 3502.3. The proposed language also removed a

reference to services that are “delegated, a now inaccurate term, as discussed above.

CCR Section 1399.540 – Subdivision (c)

Purpose: The Board is proposing to capitalize the word “Board,” strike the words “Medical Board of California or their” and add “its,” and to replace the words “he or she is” with “they are.”

Anticipated Benefits/Rationale: This proposal makes nonsubstantive changes consistent with CCR section 1399.502(a) for easier comprehension and readability of the regulation. As of October 7, 2021, the PAB is no longer within the jurisdiction of the Medical Board of California. Without statutory authority, the Board cannot require licensees to prove or demonstrate competence to the Medical Board of California or its representative, and thus that language is being struck for clarity. The proposal also seeks to remove gender-specific language and replaces it with gender-neutral language pursuant to [Assembly Concurrent Resolution No. 260 of 2018](#) (ACR 260), wherein the legislature urged state agencies to use gender neutral pronouns and avoid the use of gendered pronouns in drafting regulations.

CCR Section 1399.540 – Subdivision (d)

Purpose: This proposal would remove existing language in subdivision (d) and add language that clarifies the requirements regarding a PA’s ability to consult and make referrals.

Anticipated Benefits/Rationale: This newly proposed language requires a PA faced with a task beyond their abilities to either consult with a supervising physician or refer the patient to a licensed healthcare provider competent to render the services needed. The existing language had required the PA to only refer patients requiring services beyond the PA’s ability to a physician. This revision expands a PA’s ability to follow the existing standard of care, under which PAs presently, when appropriate, refer patients to individuals who are not physicians, but can be licensed healthcare providers, such as dentists, podiatrists, or a patient’s treating psychologist or therapist.

Amend Section 1399.541 – Medical Services Performable, initial paragraphs

Purpose: This proposal removes the existing first paragraph as it conflicts with the law since the passage of SB 697. This proposal adds in a paragraph that summarizes the law as set out in BPC section 3502. This proposal amends the existing third paragraph in this section to replace the phrase “delegation and protocols where present, protocols” with the phrase “practice agreement.” Minor grammatical changes are also proposed.

Anticipated Benefits/Rationale: This proposal seeks to clarify the PA-supervising physician relationship, which is defined in a practice agreement as set out in BPC sections 3501(k) and 3502.3. Although the term “agency” is an option in the practice agreement, it is no longer universal and is no longer required in the practice agreement. This proposal references BPC section 3502 which provides the requirements a PA must fulfill when performing medical services. Replacing the phrase “delegation and protocols where

present, protocols” with the phrase “practice agreement” is in accordance with the law after the adoption of SB 697. Grammatical corrections were made to the list of settings within this subdivision to consistently list all of the settings as singular items, unlike the previous listing of settings containing both plural and singular items.

CCR Section 1399.541 – Subdivision (c)

Purpose: This proposal would amend subdivision (c) to add an Oxford comma within the phrase “laboratory procedures, screening procedures, and therapeutic procedures.”

Anticipated Benefits/Rationale: In subdivision (c), and Oxford comma has been added for clarity.

CCR Section 1399.541 – Subdivision (i), paragraphs (1), (2), and (3)

Purpose: This proposal would amend subdivision (i) paragraphs (1) and (2) and add paragraph (3) defining the phrase “immediately available” for clarity. This proposal replaces the word “evidence” for the word “documentation” and adds paragraph (3) to define the phrase “immediately available.” This proposal also clarifies what the supervising physician must do before a PA can perform certain surgical procedures and clarifies what those certain surgical procedures are by adding the terms “under local anesthesia, procedural sedation, or general anesthesia.”

Anticipated Benefits/Rationale: This proposal seeks to clarify the level of supervision that must be agreed to between a PA and a supervising physician who has a PA perform surgical procedures on patients under general anesthesia. The Board investigated a complaint where the PA was performing surgery on a patient under general anesthesia and something went wrong. Because the supervising physician was not immediately available to return and assist, the patient died. Allowing a PA to perform surgical procedures on a patient under general anesthesia without requiring the supervising physician to be immediately available during the procedure would create an untenable risk to the lives and health of California consumers. The proposed language does not require the physical presence of the supervising physician. The proposed language merely defines what is adequate supervision when a PA is performing surgical procedures on a patient under general anesthesia. The phrase “immediately available” is amended and a definition is added as subdivision (i) paragraph (3) to clarify that the supervising physician must return and take over or advise and assist the PA if something goes wrong during a surgical procedure under general anesthesia.

CCR Section 1399.541 – Subdivision (j)

Purpose: This proposal would add subdivision (j) to set out as another task a PA can perform, obtaining patient consent for recommended treatment and documenting the consent in the patient’s medical record.

Anticipated Benefits/Rationale: This proposal adds subdivision (j) to allow a PA to obtain consent for recommended treatments and requires the consent be documented in the patient’s medical record. Without a California statute that defines or requires the task of

obtaining informed consent from a patient, and documenting that consent, the Board determined that adding the proposed clarification provides greater public protection.

CCR Section 1399.541 – Subdivision (k)

Purpose: This proposal adds subdivision (k) to clarify that the list in this section of what a PA may do under a practice agreement is not exhaustive, and that other services may be provided.

Anticipated Benefits/Rationale: This subdivision is added to make clear that the law establishes that the practice agreement determines the scope of a PA's practice, not the list in this regulation section. The practice agreement defines the medical services a PA is authorized to perform pursuant to BPC section 3502 and a practice agreement can include any additional provisions agreed to by a PA and their supervising physician.

Amend Section 1399.545 – Supervision Required

CCR Section 1399.545 – Subdivision (a)

Purpose: This proposal would amend subdivision (a) to clarify the availability requirements for a supervising physician when a PA is performing medical services for patients.

Anticipated Benefits/Rationale: This proposal clarifies that a supervising physician must be available for a PA's inquiries in person, by phone, or other means of electronic communication when a PA is providing medical services for patients. The remaining language in the subdivision is stricken as the practice agreement is where a PA and their supervising physician will set out who will cover for a supervising physician when the supervising physician is unavailable.

CCR Section 1399.545 – Existing subdivisions (b) and (c)

Purpose: This proposal would remove the existing text in CCR section 1399.545, subdivisions (b) and (c) because a PA's authority to perform medical services is now addressed in BPC section 3502, and subdivision (c) conflicted with the intent of SB 697.

Anticipated Benefits/Rationale: This proposal seeks to clarify the PA's authority by removing the contradictory language in subdivision (b). The changes to PA practice brought about by SB 697 increased the importance of the practice agreement. Pursuant to BPC section 3502, a PA is authorized to perform those medical services described in the practice agreement. The PA must also have the competency to perform the medical services, and the PA's education, training, and experience must have prepared the PA to render the services. This is a matter to be discussed by a supervising physician and a PA and determined by the supervising physician. Former subdivision (b) now contradicts the law concerning PA practice and needs to be repealed to remove any confusion. Subdivision (c) is struck because now the methods for the continuing evaluation of the competency and qualifications of the PA must be determined and agreed upon by a PA and their supervising physician, and must be included in the practice agreement, pursuant

to BPC section 3502.3.

CCR Section 1399.545 – Former subdivision (d), now subdivision (b)

Purpose: This proposal would change subdivision (d) to subdivision (b) and is amended for clarity.

Anticipated Benefits/Rationale: This proposal clarifies how procedures to be followed in an emergency shall be established. It is an important consumer protection that a PA know what procedures must be followed in an emergency before an emergency arises. The statutory changes made by SB 697 did not address this issue. Depending on where a PA works, emergency procedures may already be established, but all PAs need to have a clear understanding of what steps they are to take when an emergency beyond their training and competency occurs. To meet the Board’s consumer protection mandate, this subdivision was revised to require the practice agreement address these procedures.

CCR Section 1399.545 – Subdivision (e)

Purpose: This proposal would remove the existing text in subdivision (e) as it conflicts with the intent of SB 697.

Anticipated Benefits/Rationale: This proposal seeks to clarify the changes made by the adoption of SB 697. The existing regulatory language in subdivision (e) was written under the premise of a delegation of services agreement and mandatory chart co-signature. SB 697 removed those requirements. Pursuant to BPC section 3502, the supervising physician is no longer required to review or countersign patient medical records entered and signed by a PA, thus any reference to countersignature of medical records should be removed for clarity. SB 697 further removed requirements that the physician be physically available to the PA for consultation, thus the language requiring examination of a patient by a supervising physician the same day as care is given by the PA should be removed for clarity.

CCR Section 1399.545 – Former subdivision (f), now subdivision (c)

Purpose: This proposal would change former subdivision (f) to subdivision (c) and replace the word “autonomously” with the phrase “without supervision” for clarity. This proposal would also replace the words “his or her” with “their.”

Anticipated Benefits/Rationale: This proposal clarifies that the word “autonomous” should be replaced with the phrase “without supervision” because the word “autonomous” implies independence. The PA-supervising physician relationship is a matter between the parties to a practice agreement, which contains policies and procedures to ensure adequate supervision of the PA. The phrase “without supervision” correctly states the PA’s limits of practice because a PA is required to be supervised by at least one supervising physician. The proposal also seeks to remove gender-specific language and replace it with gender-neutral language pursuant to [Assembly Concurrent Resolution No. 260 of 2018](#) (ACR 260), wherein the legislature urged state agencies to use gender neutral pronouns and avoid the use of gendered pronouns in drafting regulations.

Underlying Data

Technical, theoretical, or empirical studies, reports, or documents relied upon (if any):

1. Agenda, relevant Meeting Materials, and Minutes of the Physician Assistant Board's August 7, 2020, meeting.
2. Agenda, relevant Meeting Materials, and Minutes of the Physician Assistant Board's November 9, 2020, meeting.
3. Agenda, relevant Meeting Materials, and Minutes of the Physician Assistant Board's February 8, 2021, meeting.
4. Agenda, relevant Meeting Materials, and Minutes of the Physician Assistant Board's November 8, 2021, meeting.
5. SB 697 (Caballero, Chapter 707, Statutes of 2019)

Business Impact

This regulation will not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the requirements of this regulation are already imposed by the statutory changes created by the passage of SB 697, so that any economic impact is not the result of this regulation.

Economic Impact Assessment

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.

Fiscal Impact:

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.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

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.