DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS
DIVISION 13.8. PHYSCIAN ASSISTANT BOARD

SB 697 IMPLEMENTATION

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: SB 697 Implementation

Section Affected: Section 1399.502 of Article 1 of Division 13.8 of Title 16 of the California Code of Regulations, 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

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein is updated as follows:

The proposed text was noticed on the Board's web site and mailed to interested parties on July 28, 2023. The 45-day comment period began on July 28, 2023 and ended on September 12, 2023. The Board did not hold a hearing and no request for a public hearing was received during the 45-day public comment period. During the 45-day public comment period, three written comments with recommendations were received. At its November 6, 2023 meeting, the comments were rejected or accepted as specified below, and the Board adopted the revised regulatory language in response to some of the comments received.

The modified text containing revisions approved at the November 6, 2023 meeting was noticed on the Board's web site and mailed to interested parties on December 5, 2023. The 15-day comment period began on December 5, 2023 and ended on December 20, 2023. During the 15-day comment period, three written comments with recommendations were received. Some of the comments were accepted, and the Board adopted revised regulatory language in response to the comments received at its March 4, 2024 Board meeting. The comments received and the Board's responses are summarized in the "Objections or Recommendations/Board Responses" section below.

The Second Modified Text approved by the Board on March 4, 2024 was noticed on the Board's web site and mailed to interested parties on March 7, 2023. The second 15-day comment period began on March 7, 2024 and ended on March 22, 2024.

The Second Modified Text was amended in response to comments as specified below. In addition, the Board made the following changes to proposed regulatory language to help avoid confusion among the regulated community regarding the impacts of the changes to the Board's Practice Act due to enactment of SB 697, and to ensure consistent enforcement of the Practice Act in accordance those changes, as follows:

Further changes were made to remove or revise text that appears to include incorrect cross-references, or be duplicative of or superseded by the amendments enacted by SB 697 at BPC sections 3502 and 3502.3, including:

(a) Striking text at CCR section 1399.540(a) and part of CCR section 1399.540(b), which simply restate BPC section 3502.3 requirements and do not clarify BPC section 3502.3 further.

(b) Striking the introductory paragraph to CCR section 1399.541 as unnecessary and superseded by the standards for supervision and authorized medical services in BPC sections 3501(f) and 3502:

~~*A physician assistant may, pursuant to Section 3502 of the Code, initiate an order or perform a task, which shall be considered the same as if the action had been ordered or performed by a supervising physician, without any prior patient-specific order of a supervising physician.*~~

(c) Correcting an existing cross-reference to reflect the newly renumbered sections that provide examples for additional medical services performable to include the newly added "(j") to this section to make more specific that such practices are included within all forms of medical services that are authorized by the practice agreement;

(d) Striking other references to personal presence requirements and limitations on surgical and anesthetic medicine in CCR section 1399.541(i) as noted below in response to CAPA's comments about the conflict with the legislative requirement forbidding a physical presence requirement per BPC section 3501(f)(1);

(e) Striking subsection (j) of CCR section 1399.541. Although the Board retains authority to specify "any other practices that meet general criteria" adopted by the Board (see BPC section 3502.3(b)), the Board members have expressed concerns that the proposed language at CCR section 1399.541(j) does not capture the correct "informed consent" standard and therefore is not reflective of current practice. As a result, the Board struck this sentence from the proposal as follows:

~~*(j) Obtain the necessary consent for recommended treatments and document the informed consent conversation and the patient's decision in the medical record.*~~

(f) Striking the word "competent" in CCR section 1399.541, subsection (j) (re-lettered from (k)) and add "qualified" and language consistent with the requirements in BPC section 3502 that must be met to perform services authorized by the practice agreement, to read to ensure all qualifying criteria for a PA to perform a medical service are met prior to practice:

(~~k~~*j*) Perform any other services authorized by the practice agreement for which the physician assistant is *qualified* ~~*competent*~~ *in accordance with the*

requirements of Section 3502 of the Code.

(g) Striking the reference to "in person" requirements for supervision in CCR section 1399.545 as inconsistent with the prohibition in BPC section 3501(f)(1).

(h) Finally, the Board deleted CCR section 1399.545((d) proposed to be renumbered to (b) originally) entirely (proposed and existing standards for written transport and back-up procedures in cases of emergency in practice agreements) because the Board can no longer require what services or protocols must be included in the practice agreement as it is determined at the practice level between the physician assistant and supervising physician(s) in accordance with BPC section 3502.

During the 15-day comment period two comments were received with one commenter in support of the Second Modified Text and another commenter objecting and providing recommendations as specified below. At its May 20, 2024 meeting, the Board reviewed the comments and approved proposed responses to reject the adverse comments received and proceeded to adopt the text as noticed in the Second Modified Text Notice. All comments and recommendations received, and the Board's responses to those comments are summarized in the "Objections or Recommendations/Board Responses" section below.

Errors in Underlying Data Corrected

The Board notes that the following information was noticed as underlying data in the Initial Statement of Reasons in error: the Board's Relevant November 9, 2020 Meeting Materials. As discussed in the meeting minutes for that meeting, the Board did not provide meeting materials for this item as discussed in the meeting minutes. In addition, in the Addendum to the Initial Statement of Reasons, the Board incorrectly reported the September 9, **2029**, Senate Floor Analysis on SB 697 when the actual year for the analysis is 2019. The Board hereby corrects the rulemaking file to delete the reference to "Relevant Meeting Materials" for the November 9, 2020 meeting and remove the reference to 2029 and replace it with 2019 (the year all stakeholders are aware that SB 697 was enacted). The Board considers these corrections to be minor technical changes as the meeting minutes disclose that the meeting materials error was disclosed to the public and the year "2029" reference is an obvious typographical error, not affecting the rights, responsibilities or duties of any person affected by the changes.

Non-Substantive Changes Made After Filing on June 6, 2024

Based on comments from the Office of Administrative Law in July 2024, the Board is making the following non-substantive changes to the regulatory text:

CCR Section 1399.502

- For the definition of "practice agreement" in proposed subdivision (e), adding "(a)" following the word "Section 3502.3" to reference the requirements of the practice

agreement as stated in Section 3502.3 of the BPC (Code)
- For the definition of "practice agreement" in proposed subdivision (e), adding "and section 1399.540(a)" following the word "Code" to make the reference consistent with the language in CCR section 1399.540(a) which requires a practice agreement to also be dated by the physician assistant and one or more authorized physicians and surgeons.

CCR Section 1399.540

- Removing a double underline between words "authorized" and "physicians" in revised subsection (a)
- Removing the authority citation in the Note to Section 2018 of the Code as it is a Medical Board of California authority citation, not this Board's authorizing statute
- Removing the authority citation Section 3502 of the Code in the Note as it is not authority to adopt a regulation but a law being interpreted by this regulation
- Removing the word "and" following "3502" in the Note for proper grammar
- Adding "s" following the word "Section" in the Note for proper grammar
- Underlining the comma following "3527" in the Note for proper punctuation
- Adding the word "Code." following "Professions" at the end of the Note to accurately reflect existing text.

CCR Section 1399.541

- Removing the words "the requirements of" following "in accordance with" in subsections (i)(1) and (i)(2), to more accurately describe the standards in Section 3502, which contains requirements as well as other restrictions on practice.
- Removing the unnecessary underline of the period in subsections (i)(1) and (2) as the period already exists as part of this existing subsection and subparagraphs.
- Removing the authority citation in the Note to Section 2018 of the Code as unrelated it is a Medical Board of California citation.
- Removing the authority citation Section 3502 of the Code in the Note as it is not authority to adopt a regulation but a law being interpreted by this regulation.
- Removing the word "and" following "3502" in the Note for proper grammar.
- Removing "s" following the word "Section" in the Note for proper grammar.
- Removing the unrelated reference citation to Section 2058 of the Code in the Note as it is a Medical Board of California citation
- Underlining the comma following "3502" for proper punctuation in the Note
- Underlining the comma following "3509" for proper punctuation in the Note

CCR Section 1399.545

- Removing the words "to receive inquiries" and comma following the word "available" in subsection (a) as the Board did not intend to revise the common understanding of what "available" means
- Removing underline between "physician" and "shall" in subsection (d) (which is

proposed to be repealed in this rulemaking) to more accurately reflect the struck text.
- Removing "s" after "Sections" in the authority citation in the Note
- Removing the unrelated authority citation to Section 2018 of the Code in the Note as it is a Medical Board of California citation
- Removing the authority citation Section 3502 of the Code in the Note as it is not authority to adopt a regulation but a law being interpreted by this regulation
- Removing the authority citation Section 3502.3 of the Code in the Note as it is not authority to adopt a regulation but a law being interpreted by this regulation
- Removing the word "and" prior to "3510" for proper grammar in the Note.

Rationale for additional amendments to CCR section 1399.540(a) (as Noticed in the Second Modified Text):

The Board proposes to strike the terms "signed and" and add a cross-reference to BPC section 3502.2 from the originally noticed text, so that the sentence reads:

In addition to meeting the requirements of Section 3502.3 of the Code, ~~A~~ a ~~delegation of services~~practice agreement shall be ~~*signed and*~~ dated by the physician assistant and one or more *authorized* physicians and surgeons.

BPC section 3502.3 contains no requirement that the practice agreement be dated. Without this information, it would be unclear whether the physician assistant was operating under a current practice agreement, which is a pre-requisite to providing medical services under the supervision of a licensed physician and surgeon as provided in BPC section 3502(a)(2). With these changes, the Board intends to centralize all practice agreement requirements in one place for the effective enforcement of the laws under its jurisdiction.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

The Board has determined that this action does not have a significant adverse economic impact on small businesses. The Board has determined that the proposed regulation would not affect small businesses because the proposal is not of sufficient magnitude to eliminate or expand businesses. This determination is based upon the fact that 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.

Anticipated Benefits

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 and thereby ensure consistency with the law enacted by SB 697 and avoid confusion in the regulated community regarding the standards applicable to practice agreements. This will help ensure consistent implementation and greater compliance with the laws and regulations enforced by the Board.

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.

Objections or Recommendations/Board Responses

Comments Received during the 45-day public comment period:
Three written comments with recommendations were received by Greg Hadfield, PA-C, Todd Primack, DO and Antonio Hernandez Conte, MD, MBA, FASA, for the California Society of Anesthesiologists (CSA), and Charlotte Tsui, Esq., for the California Medical Association (CMA).

Comments from Mr. Hadfield

Comment Summary: Mr. Hadfield's comment recounts his experience working as a Dermatology PA and notes that his experience has been both covered by a supervising board-certified dermatologist, and by a supervising physician without a dermatology, specialty credential, and does not fully know my skills or procedure or diagnostic levels, because they are not dermatology trained. He asserts that physician assistants that are initially trained by Dermatology Physicians or have the extent of experience and the specialty under any Physician are more than adequate to continue practice with the supervision of a non-dermatology provider who can advise on emergent conditions.

He states that he needs to see more studies that show dermatology trained physician assistants initially trained under a board-certified dermatologist initially have been more negligent and negligent in their standard of care or best medical practices. He feels that with his experience under both systems, and currently being under a board-certified dermatologist who's also a Mohs certified surgeon has been comfortable, but he very seldom asks for advice, most likely due to his experience, and expressed that this [proposed regulation] is a hurdle that does not need to be placed in front of a specialty that has so many holes and gaps in provision, for all of the patients in California.

Board Response: Mr. Hadfield appears to raise concerns that a PA with specialized experience be able to continue working in that specialization under a practice agreement with a non-specialist physician. The proposed regulatory changes do not forbid such an arrangement. The contours of a PAs practice, by statute, is shaped by and set out in the practice agreement between the supervising physician and the PA. Since the proposed regulatory language does not require a PA to only work under physicians that have the same area of specialization as the PA, the Board declined to make any changes to this rulemaking in response to Mr. Hadfield's comment.

The two comments from Mr. Primack and CSA were similar and request the removal of the proposed amendments to 16 CCR section 1399.540(d) and 16 CCR section 1399.541(i)(1)-(3).

Summary of CSA and CMA Comments and Recommendation One (1) (16 CCR section 1399.540(d)):

The amendments to 16 CCR section 1399.540(d) allow a PA to refer a patient to a licensed healthcare provider when the "task, procedure, or diagnostic problems exceeds" the PA's level of competence. Both CSA's and CMA's comments assert that the changes are beyond the scope of PA practice after the passage of SB 697, which added Business and Professions Code (BPC) section 3502.3(a) which reads:

"(1) A practice agreement shall include provisions that address the following:

> (A) The types of medical services a physician assistant is authorized to perform.
> (B) Policies and procedures to ensure adequate supervision of the physician assistant, including, but not limited to, appropriate communication, availability, consultations, and referrals between a physician and surgeon and the physician assistant in the provision of medical services."

A referral to another licensed health care practitioner falls within the definition of medical services provided by physicians. Under BPC section 3502.3, the scope of a PA's practice is established in the practice agreement. CSA and CMA are asking the Board to restricting PAs from making referrals, a restriction on PA practice that goes beyond BPC section 3502.3. If the practice agreement doesn't address making referrals to licensed health care providers, then a PA is not authorized to make referrals.

Board Response to CSA and CMA Comments and Recommendation No. 1:

The Board finds that a practice agreement can contain policies and procedures to ensure adequate supervision of a PA such that the PA is authorized to refer patients to one or several specified providers or groups of providers. The Board declines to require an extra layer of referrals in every instance which could delay the speed of obtaining care. The changes made by SB 697 "generally allows supervising physicians to determine the appropriate level of supervision for PA practice;" and "the supervising physician's license is subject to discipline for any patient harm resulting from a PA's practice if the physician does not perform the appropriate oversight." (quoting from the Senate Rules Committee report on SB 697, attached, in the Digest and Background sections, respectively). The Board believes it is fulfilling its public protection mandate consistent with BPC section 3504.1 by allowing supervising physicians and PAs to define within the practice agreement if and how a PA can refer patients to other licensed healthcare providers, and the appropriate supervision needed.

The CSA and CMA comments both raise the concern that a PA might refer a patient to another PA or a nurse practitioner. If a supervising physician knows of a PA or nurse

practitioner with the experience and expertise to provide a needed service for a particular task, procedure, or diagnosis, they can make a referral to them. A practice agreement can contain the necessary policies and procedures for a PA to be authorized to make referrals to a PA or a nurse practitioner under the terms of BPC section 3502.3. The Board declines to single out and remove the act of providing referrals from the scope of medical services a PA can perform if providing referrals are allowed and adequately supervised under the practice agreement. However, the Board finds the language in proposed 16 CCR section 1399.540(d) could benefit from minor editing for clarity. The Board proposes to adopt Modified Text that states that a PA faced with a task, procedure, or diagnostic problem beyond their level of competence can either consult a supervising physician or refer to a physician and surgeon or licensed healthcare provider.

Summary of CSA and CMA Comments and Recommendation No. 2 (16 CCR section 1399.541(i)(1)):

The CSA and CMA comments both request the Board remove the proposed amendments to 16 CCR section 1399.541(i)(1)-(3). The amendments to 16 CCR section 1399.541(i)(1) allow a PA to perform surgeries on a patient undergoing procedural sedation without the personal presence of the supervising physician and replace the requirement of the personal presence of the supervising physician when a PA is performing a surgery on a patient under general anesthesia with the requirement that the supervising physician be immediately available during the procedure. Both comments argue that allowing PAs to perform surgeries on a patient under procedural sedation or general anesthesia without the personal presence of the supervising physician is beyond the scope of PA practice after the passage of SB 697. The CSA comment characterizes procedural sedation as “a concept created by emergency room physicians to enable intravenous general anesthesia for short procedures without the presence of anesthesiologists.” CSA also provides the Board with an article from the ASA Monitor entitled “Anesthesiology Oversight for Procedural Sedation.” CSA urges the Board to consider that due to the variability in sedation practices and patient responses, procedural sedation can result in loss of protective airway reflexes and spontaneous ventilation. The CMA comment asserts the proposed regulatory language is following the definition of procedural sedation in the national guidelines from the America College of Emergency Physicians (ACEP) and argues using the term “procedural sedation” makes the regulation unclear.

Both the CSA and CMA comments emphasize that sedation is a continuum and it is not always possible to predict how an individual patient will respond under sedation and cite to the American Society of Anesthesiologists (ASA). The CSA comment includes the ASA “Statement on Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia”).

The CSA comment includes the ASA “Statement on ASA Physical Status Classification System,” and notes that assigning an ASA Physical Status classification level is a clinical decision for which PAs lack the requisite education and training to make this assessment prior to a patient submitting to surgery.

Board Response to CSA and CMA Comments and Recommendation No. 2:

The Board agrees that the term “procedural sedation” does not have a clear definition, and the regulation would benefit from removing the term. In the proposed Modified Text, the Board is removing the phrase “procedural sedation” altogether, and instead using the phrase “sedation other than local anesthesia, including general anesthesia.”

The Board has carefully reviewed the CSA and CMA comments and proposes to modify the proposed regulatory language to move how surgical procedures on a patient under procedural sedation are regulated so that those procedures are regulated in the same manner as surgery on a patient under general anesthesia. In the interests of public protection, the Board proposes modifications to the proposed language in 16 CCR section 1399.541(i)(1) that make this change.

The Board agrees that the determination of the patient’s status and fitness for surgery is best made by a physician, and not a PA. Just as the existing regulation requires the supervising physician to review and reach a determination each time that the PA is adequately trained and qualified to perform the surgical procedure under the proposed level of sedation, the Board proposes to add language to 16 CCR section 1399.541(i)(1) that requires: “The physician assistant shall ensure the supervising physician and surgeon has performed an assessment of whether the patient’s physical status and fitness is appropriate to undergo the procedure.“ This modification makes clear that each time, the supervising physician must assesses the appropriateness of the PA performing the surgical procedure given the procedure involved, the patient, and the level of sedation, and the supervising physician must also assess whether the patient’s physical status and fitness is appropriate to undergo the procedure under the planned level of sedation.

The Board notes the concerns expressed by CSA regarding surgeries performed under procedural sedation without an attending anesthesiologist. The Board seeks only to facilitate supervising physicians deciding, based on their knowledge of the training and experience of their PA, what surgical procedures the supervising physician is willing to authorize the PA to perform under appropriate supervision. BPC section 3502.3 makes clear that the supervising physician and the PA must agree to what medical services the PA can perform, and the practice agreement must set out the policies and procedures to ensure adequate supervision of the PA when the PA is performing the medical services.

A physician could have a PA with years of experience acting as a first or second assistant in surgeries where the patient was under procedural sedation or general anesthesia. The Board does not believe the Board’s regulations should categorically forbid a supervising physician from authorizing a PA to perform surgical procedures under sedation other than local anesthesia, including general anesthesia under appropriate supervision. The Board notes, the supervising physician has actual knowledge of the PA’s training, experience, and skill, and the supervising physician remains ultimately responsible for any harm resulting to the patient if the supervising physician does not exercise appropriate oversight.

BPC section 3502.3 does not carve out or forbid a supervising physician and a PA from putting language in the practice agreement that authorizes a PA to perform surgery on patients under sedation other than local anesthesia, including general anesthesia, with appropriate supervision. Both the CSA and CMA comment letters refer to language that had been initially included in SB 697 when the bill was introduced that was subsequently removed as supporting a statutory requirement that the supervising physician must be physically present during certain surgical procedures.

In the legislative process, changes are made for a myriad of reasons. Both comment letters assert patient safety concerns were behind the changes made, but such concerns are not discussed or made clear in any of the bill reports for SB 697. On the contrary, the initial April 18, 2019, Senate Business, Professions and Economic Development report on SB 697, states that the bill: "Prohibits "supervision" from requiring the physical presence of the physician and surgeon." (on p.3. as Item 3.) This exact language is repeated in the May 18, 2019, Senate Floor Analysis (again on p.3, as Item 3), and in the July 8, 2019, Assembly Committee Business and Professions Analysis (on p.2, as Item 1). The final statutory language incorporates that thrice-repeated legislative intention in BPC section 3501(f):

"(1) Supervision, as defined in this subdivision, shall not be construed to require the physical presence of the physician and surgeon, but does require the following:

(A) Adherence to adequate supervision as agreed to in the practice agreement.

(B) The physician and surgeon being available by telephone or other electronic communication method at the time the PA examines the patient.

(2) Nothing in this subdivision shall be construed as prohibiting the board from requiring the physical presence of a physician and surgeon as a term or condition of a PA's reinstatement, probation, or imposing discipline."

The Legislature also did not choose to include language requiring the physical presence of the supervising physician in the acute care hospital setting, instead, opting for a supervision model even in hospitals. BPC section 3502(f) states only that: "(f) Notwithstanding any other law, a PA rendering services in a general acute care hospital as defined in Section 1250 of the Health and Safety Code shall be supervised by a physician and surgeon with privileges to practice in that hospital. Within a general acute care hospital, the practice agreement shall establish policies and procedures to identify a physician and surgeon who is supervising the PA."

Because BPC section 3501(f) prohibits the term "supervision" from being construed to require the physical presence of the supervising physician, the Board will not attempt to require the supervising physician's physical presence during certain surgical procedures in regulation. The Board is attempting to strike a balance between the best protection of the public and the specifically stated legislative intent by requiring the next highest level of supervision, which is to require the supervising physician be "immediately available" to respond to any exigent circumstances.

Both CSA's and CMA's comments assert that PAs do not have the requisite training in airway interventions for the support of patient ventilation and oxygenation. Both comments also assert the proposed changes would exacerbate the incident discussed in the Initial Statement of Reasons describing an investigation in which a PA performing a surgical procedure was unable to get the supervising physician to return and assist, and the patient died. The Board is imposing the requirement that the supervising physician be "immediately available" when a PA is performing a surgical procedure on a patient under "sedation other than local anesthesia, including general anesthesia" as the next most stringent supervision available for the Board to impose, given that supervision cannot be construed as requiring the physical presence of the supervising physician (BPC section 3501(f)(1)).

Under BPC section 3502.3, the supervising physician must provide adequate supervision commensurate to the type of medical services being provided by the PA. This is intended to protect the public by requiring the supervising physician to consider the appropriate supervision for each delegated task. This also incentivizes the supervising physician to make clear in the practice agreement the policies and procedures that must be followed for a PA to perform various medical services. The Board has not found supervising physicians are allowing PAs to perform procedures beyond the PA's level of training and experience. While the Board understands CSA's and CMA's stances that "personal presence" of the supervising physician is required for every surgery involving general anesthesia or procedural sedation, the Board does not agree that this is true in all circumstances.

After the passage of SB 697, the supervising physician has the authority to determine the appropriate supervision for all tasks performed by a PA, including surgery. Under the prior proposed modifications, a supervising physician must evaluate the PA's skills, the patient's status and fitness, and any other relevant factors before each surgery. If a supervising physician chooses to have a PA perform surgery on a patient under sedation other than local anesthesia, including general anesthesia, in those circumstances, the Board will require the supervising physician be "immediately available" to the PA. The proposed regulatory changes, as modified, do not stop a supervising physician from stating in the practice agreement that the physical presence of the supervising physician is required whenever the PA performs certain surgeries. The supervising physician is fully invested in not authorizing a PA to perform a surgery without appropriate supervision. The proposed regulatory changes, as modified, require the supervising physician to think through the circumstances surrounding a particular patient and surgery, including the skill of the PA and the level of sedation required, and consider the impact of those factors on what would be considered appropriate supervision for the PA performing that particular procedure. As noted above, "the supervising physician's license is subject to discipline for any patient harm resulting from a PA's practice if the physician does not perform the appropriate oversight." (September 9, 2023, Senate Floor Analysis on SB 697 (p.3, under Background).

The supervising physician who is ultimately responsible for the patient must decide whether their personal presence is what constitutes appropriate supervision for a particular surgery by a PA on a patient. A supervising physician is always able to state in

the practice agreement when their personal presence is required for a PA to perform surgery. The Board declines to require the "personal presence" of the supervising physician in regulation in contravention to the express language in BPC section 3501(f)(1). The Board believes the proposed regulatory changes, as modified, strike an appropriate balance between public protection and the statutory changes made with the passage of SB 697.

Summary of Comments and CSA and CMA Recommendation No. 3: The CSA and CMA comments do not raise any specific objections to the proposed non-substantive change to 16 CCR section 1399.541(i)(2) and (3). The change to those two paragraphs is typographical in nature, moving the last sentence of 16 CCR section 1399.541(i)(2) to stand alone as 16 CCR section 1399.541(i)(3). The definition was not changed. The objections raised are to when "immediately available" supervision is allowed, but not to the definition itself.

CSA notes the "immediately available" standard for the supervising physician in these instances is NOT appropriate nor within the standard of care for these procedures. Therefore, CSA strongly recommends that these additions regarding "general anesthesia" be struck from the regulations or require the "personal presence" of the supervising physician when a physician assistant is performing surgery on a patient under general anesthesia. Patients can undergo major life-threatening major life-threatening complications during surgery that could only take a matter of seconds and/or minutes to kill a patient.

CMA notes the proposed regulations also change the supervisory standards for general anesthesia procedures; previously the "personal presence" of a physician was required for PAs to perform surgical procedures requiring other forms of anesthesia besides local anesthesia, but now the physician must simply be "immediately available" according to a definition that appears to remove the physical presence element.

Board Response to Recommendation No. 3: The Board acknowledges receipt of the comments but notes that the change made in the proposed amendments was non-substantive. With respect to the "immediately available" definition, at the time, the Board did not see a need to make changes to revise 16 CCR section 1399.541(i), paragraphs (2) and (3) for the reasons set forth in response to CSA and CMA Comments and Recommendation No. 2 above. However, upon reconsideration, the Board does address these concerns in response to comments received during the Modified Text public comment period and with the Second Modified Text changes described below.

Comments Received during the 15-day public comment period for the Modified Text:

Three written comments with recommendations were received by the California Academy of PAs (CAPA), the California Medical Association (CMA), and California Orthopaedic Association (COA)

Summary of Comment from CAPA

Comment No. 1: CAPA argues that the proposed regulation section for CCR section

1399.541 as noticed in the Modified Text does not accurately reflect the changes proposed from the Originally Proposed Regulatory Language noticed on July 28th. They note that the words "or sedation other than local anesthesia" are new to the December 5th language, yet they are not double underlined to accurately show the public what is proposed to be added by the Board.

Comment No. 2: The CAPA comment proposes a grammatical sentence correction to delete the word "Performance" and restore the word "Perform" to the beginning of the sentence in CCR section 1399.541(i)(1).

Comment No. 3: CAPA objects to the proposed requirements in subsection (i) of CCR section 1399.541 that would require a physician assistant to "ensure" that a supervising physician and surgeon both "reviews the evidence which indicates that the physician assistant is trained and qualified to perform the surgical procedures under such sedation" and "has performed an assessment of whether the patient's physical status and fitness is appropriate to undergo the procedure." CAPA argues the Board's proposal flips the legally established relationship between PA's and supervising physicians and surgeons upside down by attempting to establish a PA supervisorial relationship over a supervising physician and surgeon. The commenter asserts that current law establishes a physician and surgeon supervisory relationship with PAs through practice agreements contradicting this proposal (see specifically, Business and Professions Code (BPC) section 3501(f)). A regulatory proposal by the Board that mandates that a PA "ensure" that a physician and surgeon do anything, including reviewing the training qualifications of PAs and conducting patient assessments, is unlawful and there is no statutory authority that will lawfully enable a PA to instruct physicians and surgeons to do anything. This is illustrated in BPC section 3502.3(a)(1)(c) which states the methods for the continuing evaluation of the competency and qualifications of the physician assistant, which is determined in the practice agreement between the physician assistant and supervising physician and surgeon.

Further, BPC section 3502 establishes a PA's right to practice no matter what any other law or regulation provides. BPC section 3502 states in pertinent part:

> "(a) Notwithstanding any other law, a PA may perform medical services as authorized by this chapter if the following requirements are met:
> (1) The PA renders the services under the supervision of a licensed physician and surgeon…" (Emphasis added.)

The commenter further cites to Assembly Business and Professions Code analysis and explanation of SB 697, dated July 9, 2019, where the analysis states that the purpose of SB 697 was to eliminate the statutory requirements for administrative oversight by physicians and instead requires physicians and PAs "to determine for themselves the appropriate level of supervision."

This requirement to "ensure" assessments are performed also conflicts with other sections of the Board's proposed regulations, including, proposed text at CCR section 1399.541, which states, in part:

"A physician assistant may, pursuant to Section 3502 of the Code, initiate an order or perform a task, which shall be considered the same as if the action had been ordered or performed by a supervising physician…"

Comment No. 4: Further, CAPA states that the new proposal regarding assessments is not accurate as an assessment performed by the PA is not the same as one performed by the supervising physician and that the proposal contradicts CCR section 1399.541(a).

Comment No. 5: CAPA asserts that the proposed regulatory text at subsection (i) of CCR Section 1399.541 is not consistent with medical terminology. The commenter states the prior regulation correctly enumerated local anesthesia, procedural sedation, and general anesthesia, and that the proposed modified text proposal incorrectly asserts a hierarchical medical relationship between "sedations," i.e., that "local anesthesia" is always a subcategory of "sedation", and the regulation incorrectly states "general anesthesia" is a form of sedation different from "local anesthesia". CAPA recommends deleting subsection (i) altogether or revising the proposal as set forth in its comment letter, and as previously suggested in its November 13th, 2020 response (the Board received a comment dated November 12, 2020, see Attachment 6).

Board Responses to Comments from CAPA:
Response to Comment No. 1: The Board accepts this comment and corrects the text as noted in the comment letter.

Response to Comment No. 2: The Board accepts this comment and corrects the text as noted in the comment letter.

Response to Comment No. 3: The Board accepts this comment and is striking the language that requires PAs to "ensure" their supervising physician reviews their qualifications or performs an assessment as described above. The Board would agree that these reviews and assessments are determined at the practice level in the practice agreement and by meeting the requirements in BPC section 3502.

Response to Comment No. 4: As noted in the response above, the Board has decided to strike this language as it interprets BPC sections 3502 as already prescribing the minimum standards for medical services a physician assistant can perform.

Response to Comment No. 5: BPC section 3502.3 does not carve out or forbid a supervising physician and a physician assistant from putting language in the practice agreement that authorizes a physician assistant to perform surgery on patients under sedation other than local anesthesia, including general anesthesia, with appropriate supervision. Therefore, the Board is striking these references to anesthetic medicine because the supervision requirements can be determined at the practice level in the practice agreement and in accordance with the requirements in BPC section 3502.

Summary of Comment from CMA:
Comment No. 1: The CMA comment proposes to amend 16 CCR section 1399.541(i)(1)

to continue to place review of a physician assistant's qualifications on the supervising physician and surgeon, and to prevent a physician assistant from performing any procedures until that has happened. CMA is also requesting the Board change the word "evidence" to "documentation" as it is more difficult to determine what qualifies as "evidence".

Comment No. 2: CMA further suggests excluding surgical procedures performed using local anesthesia from this requirement. CMA believes this could disrupt current practice as the current regulations allow physician assistants to perform surgery under local anesthesia without the personal presence of the supervising physician and surgeon and do not currently require an assessment prior to such a procedure.

Comment No. 3: Further, the CMA comments suggests the addition of the paragraph "Nothing in this section shall prohibit one or more supervising physicians and surgeons or a supervising physician and surgeon who is authorized to approve the practice agreement on behalf of the physicians and surgeons on the staff of an organized health care system in accordance with Section 3502.3(a)(2)(B) of the Business and Professions Code from requiring the personal presence of a physician and surgeon when a physician assistant is performing any medical service, including surgical procedures, authorized through the practice agreement." CMA states that this paragraph would clarify that although the law cannot compel personal presence, the supervising physician and surgeon retains this discretion and may choose to require personal presence in a practice agreement with a physician assistant.

Board Response to Comment from CMA:
Response to Comment No. 1: The Board acknowledges the comment and agrees that the review of a physician assistant's qualifications is the responsibility of the supervising physician and surgeon. This is illustrated in BPC section 3502.3(a)(1)(c) which states the methods for the continuing evaluation of the competency and qualifications of the physician assistant is determined in the practice agreement between the physician assistant and supervising physician and surgeon. Therefore, the Board is striking the language at issue as the review of the qualifications and competency of the physician assistant is determined at the practice level in the practice agreement in accordance with the requirements in BPC section 3502.

Response to Comment No. 2: The Board has accepted the comment and stricken reference to "local anesthesia" because a physician assistant's ability to perform surgical procedures requiring local anesthesia can be addressed in the practice agreement as authorized by BPC section 3502.

Response to Comment No. 3: The Board acknowledges this comment but does not agree to this addition as BPC section 3502.3(a)(1)(B) states that policies and procedures to ensure adequate supervision of the physician assistant are determined in the practice agreement, which is agreed upon by the physician assistant and supervising physician and surgeon and adding a personal presence requirement of any kind through regulation would conflict with BPC section 3501(f)(1) (supervision "shall not be construed to require the physical presence of the physician and surgeon."). This does not prevent the parties

to any practice agreement from agreeing to require the personal presence of a physician and surgeon, and it is agreed upon between the supervising physician and surgeon and physician assistant as illustrated in the practice agreement. In accordance with this determination, the Board will be amending its proposal to strike any current or proposed references to “in-person” or “personal presence” requirements.

Summary of Comment from COA:
The COA comment recommended removing the term “the supervising” from CCR section 1399.541(i)(1) because any physician and surgeon can clear a patient for surgery, not just the supervising physician and surgeon. The Board has amended the text in CCR section 1399.541(i)(1) which includes removing “the supervising”. Further, COA in agreement with CMA requests that adding the paragraph “Nothing in this section shall prohibit one or more supervising physicians and surgeons or a supervising physician and surgeon who is authorized to approve the practice agreement on behalf of the physicians and surgeons on the staff of an organized health care system in accordance with Section 3502.3(a)(2)(B) of the Business and Professions Code from requiring the personal presence of a physician and surgeon when a physician assistant is performing any medical service, including surgical procedures, authorized through the practice agreement” would add clarification to CCR section 1399.541.

Board Response to Comment from COA: For the reasons noted in the responses to CMA above, the Board finds adding this paragraph is not authorized, and possibly is redundant as it simply refers to Business and Professions Code (BPC) section 3502.3(a)(2)(B) and does not clarify the statute further.

Comment Received during the second 15-day public comment period for the Second Modified Text:

The Board received two comment letters: one in support of the proposed Second Modified Text from Scott Martin, PA-C, President, on behalf of the California Academy of PAs (CAPA), and another comment letter with recommendations from Sheirin Ghoddoucy, Senior Legal Counsel, on behalf of the California Medical Association (CMA).

CAPA Comment Letter dated March 20, 2024

Comment Summary: The comment offers CAPA’s enthusiastic support to the proposed regulatory language by the Physician Assistant Board (PAB) released March 7, 2024 (Second Modified Text), and commends the PAB for its proposed amendments, which correctly implement the legislative intent of SB 697. The letter outlines the amendments proposed by the Board in the Second Modified Text and provides additional arguments in support of the amendments proposed by the Board.

Board Response to the CAPA comments: The Board has considered this comment, accepted the support, and intends to proceed with the adoption of the proposed language as set forth in the Second Modified text.

CMA comment letter dated March 22, 2024

Summary of CMA Comment No.1: CMA agrees that the prior language requiring a PA to "ensure" that a supervising physician review a PA's training improperly places the supervising physician's responsibility on the PA. However, CMA disagrees with the argument that the PAB lacks authority to impose any requirements on the verification of a PA's training and qualifications beyond the existence of a practice agreement. Accordingly, the statute authorizes a requirement to confirm a PA's competency and training independent of and in addition to the requirement of having a practice agreement in place authorizing a PA to perform certain services. The Board has authority to implement and make specific the requirements of all of subdivision (a) of BPC section 3502, including paragraphs (3) and (4).

Because performing surgical procedures under anesthesia or sedation requires specific training and carries heightened risks to patient safety, CMA argues that it is appropriate to reiterate that in the implementing regulations by requiring supervising physicians to confirm a PA meets those requirements. As a result, CMA recommended a modification to 16 CCR 1399.541(i)(1) that adds language requiring the supervising physician to review documentation when a physician assistant performs surgical procedures under anesthesia or sedation, as follows:

> Perform surgical procedures as authorized by the practice agreement and in accordance with the requirements of Section 3502 of the Code. ***A physician assistant shall not perform surgical procedures under anesthesia or sedation, unless the supervising physician reviews documentation which indicates that the physician assistant is trained and qualified to perform the surgical procedures under such anesthesia or sedation.*** (Emphasis in original.)

Board Response to CMA Comment No. 1: The Board acknowledges receipt and review of this comment but has decided to not make the modifications suggested by CMA for the following reasons.

SB 697 struck the Board's previous rulemaking authority at BPC section 3502 to establish "alternative mechanisms" for the adequate supervision of physician assistants by regulation. This was section 3 of the bill, BPC section 3502(c)(3). Instead, BPC section 3502 provides that "(a) Notwithstanding any other law, a PA may perform medical services as authorized by this chapter" if a specified list of requirements are met. Those include:

(1) The PA renders the services under the supervision of a licensed physician and surgeon who is not subject to a disciplinary condition imposed by the Medical Board of California or by the Osteopathic Medical Board of California prohibiting that supervision or prohibiting the employment of a physician assistant.

(2) The PA renders the services pursuant to a practice agreement that meets the requirements of Section 3502.3.

(3) The PA is competent to perform the services.

(4) The PA's education, training, and experience have prepared the PA to render the services.

As discussed above in response to comments for the first Modified Text for CMA's comments, BPC section 3502 sets out the complete list of criteria that must be met to authorize a PA to perform medical services in compliance with the Physician Assistant Practice Act. Nowhere in that list is a PA required to meet other regulatory requirements established by this Board prior to practicing pursuant to a practice agreement.

Regulations Counsel has advised that where the words "Notwithstanding any other provision of law" appears in a statute, the requirements that follow control in interpreting the requirements for practice. As the California Court of Appeal has stated, "The phrase has a special legal connotation; it is considered an express legislative intent that the specific statute in which it is contained controls in the circumstances covered by that statute, despite the existence of some other law which might otherwise apply to require a different or contrary outcome. (*In re Summer H.* (2006) 139 Cal.App.4th 1315, 1328.).

Legislative history for SB 697 further supports this interpretation. In the Assembly Business and Professions Committee Analysis dated July 1, 2019 ("Committee Analysis") and included in this rulemaking as underlying data, the analysis states, in part, on p. 5:

> However, modern medical practice comes in many forms. According to the sponsors, the statutory limitations on case reviews and the single physician supervision model is overly burdensome and duplicative of other protections built into the healthcare system, such as credentialing and privileging in organized health systems.
>
> To reduce those duplicative requirements, this bill eliminates the statutory requirements for administrative oversight by physicians and instead requires physicians and PAs **to determine for themselves the appropriate level of supervision, with every licensee involved in a specific practice agreement subject to discipline for improper supervision**. Rather than require a statutory number of case reviews or meetings, this bill would require the physicians and PAs to outline the necessary details for the Medical Board of California and the PAB to determine whether patient harm was the result of individual incompetence or an improperly developed practice agreement. (Emphasis added.)

The Board also notes that in its comments in support of SB 697 in the Committee Analysis, CMA wrote, in part:

> "CMA is dedicated to improving access and affordability to health care. One way to achieve this goal is to ensure physicians can assemble a full team of qualified health professionals to care for patients. Current administrative hurdles diminish incentives to working with physician assistants, and often result in physicians supervising less

physician assistants than the law would allow. This means that the physician and their team are not at the full capacity of patients they could serve."

[This bill] addresses these administrative hurdles specifically through … easing restrictions in the current delegated services agreement between physicians and physician assistants and transitioning this agreement into a Practice Agreement which will allow for the agreement to serve the relationship of a physician assistant and physicians in a practice, instead of to an individual physician.

Finally, [This bill] allows **for more autonomy to each medical practice as to their functional relationship with their physician assistants.** We believe these **administrative fixes will help to alleviate the burdens of working with physician assistants** and increase the capacity of physicians and physician assistants to address critical access to care." (Committee Analysis, p. 6; emphasis added.)

To avoid conflict with the express authority given to PAs listed in BPC section 3502 and the legislative intent noted above that was apparently acquiesced to by CMA in their comments of support for SB 697, the Board declines to make the modifications requested by this commenter.

Summary of CMA Comment No. 2: CMA objects to the Board's proposed deletion of language in 16 CCR § 1399.541(i)(1) and (2) that required a supervising physician to be immediately available when a PA performs or participates in surgical procedures under anesthesia or sedation, as well as deletion of a definition of "immediately available" in paragraph (i)(3).

According to CMA, performing surgical procedures under anesthesia or sedation carries heightened risks to patient safety. Accordingly, it is appropriate for the Board's regulations to require the immediate availability of a physician, unless the supervising physician has determined that the PA is sufficiently trained and qualified to perform these procedures without the immediate availability of a physician. To that end, CMA recommends the following revisions to CCR Section 1399.541(i):

(3) A practice agreement shall not authorize a physician assistant to perform surgical procedures under anesthesia or sedation, without either the personal presence of the supervising physician or a physician immediately available to the physician assistant, unless the supervising physician reviews documentation which indicates that the physician assistant is trained and qualified to perform the surgical procedures under such anesthesia or sedation without the presence or immediate availability of a physician.

(4) "Immediately available" when used in this section means a supervising physician is physically accessible and able to attend to the patient, without any delay, to address any situation requiring a supervising physician's services. (Emphasis in original.)

Board Response to CMA Comment No. 2: The Board acknowledges receipt and review of this comment but has decided to not make the modifications suggested by CMA for the following reasons. The Board incorporates by reference the arguments made in response to CMA Comment No. 1 above. In addition, the Board provides the following rationales for rejecting this recommendation.

The plain meaning of BPC section 3501 controls

The Board reiterates that BPC Section 3501(f)(1) specifies that supervision "shall not be construed to require the physical presence of the physician and surgeon," but does require the following:

(A) Adherence to adequate supervision **as agreed to in the practice agreement**.

(B) The physician and surgeon **being available by telephone or other electronic communication method** at the time the PA examines the patient. (Emphasis added.)

The Board is only authorized to limit PA practice under the authority in BPC section 3501(f)(2), which states, "[n]othing in this subdivision shall be construed as prohibiting the board from requiring the **physical presence** of a physician and surgeon **as a term or condition of a PA's reinstatement, probation, or imposing discipline**." (Emphasis added.)

These criteria are specific and the list absolute, leaving the Board discretion to require personal presence only as a term or condition of a PA's reinstatement, probation or in cases where the Board is imposing discipline. As a result, the Board presumes the Legislature meant what it said and will enforce the law as written.

The Board is not authorized to rewrite the statute.

The Board notes that nowhere in the above definition in BPC section 3501(f) is the Board authorized to set a physical presence requirement by Board regulation. Instead, CMA asks the Board to read the word "shall" out of the statute and adopt regulations that add another item to the list of eligibility criteria in BPC section 3501(f), an interpretation the Board cannot accede to in violation of Government Code section 11342.2 (a law that renders regulations invalid unless authorized and not inconsistent with the Board's enabling laws).

Regulations Counsel advises that the courts have found that the word "shall" is usually mandatory. As the California Court of Appeal has said:

> "It is well settled that the word "shall" is usually construed as a mandatory term. (*Common Cause v. Board of Supervisors* (1989) 49 Cal.3d 432, 443, 261 Cal.Rptr. 574, 777 P.2d 610.) This is particularly true here where to construe the statute as optional would render it ineffective, a construction that we must avoid." (*Malek v. Blue Cross of California* (2004) 121 Cal.App.4th 44, 64.)

The legislative history supports the Board's interpretation.

Finally, a review of the Legislative history for this bill shows that the Board raised concerns about removal of the physical presence requirement and the Board's regulatory authority in its original opposition to the bill while it was undergoing review in the Legislature. Pages 7 and 8 of the Committee analysis reads in part:

> "The Physician Assistant Board is opposed unless amended, seeking:.
>
> . . .
>
> 2) **An amendment to the definition of "supervision" to allow for the physical presence of a physician,** arguing that the language "shall not be construed" prevents the board and the Medical Board of California from disciplining a licensee when patient harm resulted from a practice agreement that did not require physical presence;
> 3) The striking of the language limiting regulations to those in effect June 7, 2019, as well as **reauthorizing the board to establish regulations that limit the services a PA may perform (Emphasis added.)"**

As noted in the Committee analysis on p.8 and in the resulting text enacted at BPC sections 3501 and 3502, the Board's concerns were addressed in part and rejected in part. The Legislature removed the offending "June 7, 2019" language that would have prevented the Board from adopting any new regulations after June 7, 2019, but only authorized the Board to specify limitations on practice and physical presence as set forth in BPC section 3501(f)(2) (i.e., as a term or condition of a PA's reinstatement, probation, or imposing discipline). The Legislature also did not grant the Board's request to allow it to continue to limit the services a PA may perform by regulation.

As a result of the foregoing, the Board believes the Second Modified Text accurately reflects the interpretation of its regulatory authority and the medical services performable by a PA consistent with SB 697 and declines to make the modifications requested by this commenter.

Summary of CMA Comment No. 3: Finally, CMA objects to the deletion of CCR section 1399.545(b) as noted in the Second Modified Text, which required a practice agreement to establish procedures for the immediate care of patients in need of emergency care beyond the PA's training and competency.

CMA argues that BPC 3502.3 requires practice agreements to address, in part, "[p]olicies and procedures to ensure adequate supervision of the physician assistant, including, but not limited to, appropriate communication, availability, consultations, and referrals between a physician and surgeon and the physician assistant in the provision of medical services." (BPC § 3502.3(a)(1)(B) (emphasis added).) SB 697 also repeatedly includes competency, qualifications, and training among the statutory criteria a PA and a practice agreement must satisfy in order to authorize the PA to perform medical services. (See

BPC §§ 3502(a)(2) & (3), 3502.3(a)(1)(C).) CMA argues that the Board is authorized to implement this statutory requirement through rulemaking, including but not limited to imposing specific requirement for complying with this statutory criterion, among others in BPC 3500 et seq.

Accordingly, CMA argues that the Board is within its legal authority to specify that a practice agreement must, at a minimum, include procedures for the immediate care of patients in medical emergencies where the necessary care is beyond the scope of services a PA is authorized to perform according to the practice agreement. CMA therefore recommends that the Board restore the language proposed to be deleted in CCR section 1399.5(b).

Board Response to CMA Comment No. 3: The Board acknowledges receipt and review of this comment but has decided to not make the modifications suggested by CMA. As noted in prior responses to CMA and for the reasons set forth in response to comments nos. 1 and 2, the Board can no longer generally limit the services a PA can provide in a practice agreement except in those instances specified in BPC section 3501(f)(2). SB 697 has changed the law so that such determinations are generally determined at the practice level between the physician assistant(s) and supervising physician(s) in accordance with BPC section 3502.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board as part of public comments received or at the Board's meetings would be more effective in carrying out the purpose for which the regulations are proposed, or would be as effective and less burdensome to affected private persons than the adopted regulations, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. All recommendations provided during this rulemaking were considered by the Board and either accepted or rejected as discussed herein.