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MEMORANDUM

DATE	May 6, 2024
TO	Physician Assistant Board (Board)
FROM	Kristy Schieldge, Regulations Counsel, Attorney IV Jasmine Dhillon, Legislative and Regulatory Specialist
SUBJECT	**11. Discussion and Possible Action on Rulemaking Proposal to Amend Title 16, California Code of Regulations (CCR) Sections 1399.502, 1399.540, 1399.541, and 1399.545 – SB 697 Implementation:** **A. Consideration of Public Comments Received During the 15-Day Public Comment Period on Second Modified Text and Proposed Responses Thereto** **B. Consideration of Adoption of Amendments to CCR, Title 16, Sections 1399.502, 1399.540, 1399.541, and 1399.545 to Finalize the Current Rulemaking** **C. Consideration of Proposal to Authorize Initiation of a New Rulemaking to Amend CCR, Title 16, Sections 1399.502, 1399.540, 1399.541, and 1399.545**

Background

Senate Bill (SB) 697 (Caballero, Chapter 707, Statutes of 2019) made numerous changes to the Physician Assistant Practice Act ("Act" – commencing at Business and Professions Code (BPC) section 3500 and following). At the August 7, 2020, Board meeting the Board discussed and voted to make amendments to all of the Board's regulations impacted by the SB 697 changes. The 45-day public comment period began on July 28, 2023 when the Board's Notice of Proposed Regulatory Action, Initial Statement of Reasons, and Proposed Regulatory Language were posted on the Board's website and published by the Office of Administrative Law (OAL).

Since the close of the first 45-day public comment period, there have been two modified text notices provided in response to comments received. The first modified text comment period began on began on December 5, 2023 and ended on December 20, 2023, and the Board received three public comments. At the March 4, 2024 Board meeting, the Board approved the Second Modified Text and adopted the revised regulatory language in response to the comments received. A second 15-day public comment period on the Second Modified Text began on March 7, 2024 and ended on March 22, 2024, and 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 objections and recommendations from Sheirin Ghoddoucy, Senior Legal Counsel, on behalf of the California Medical Association (CMA).

Board staff is requesting that the Board review the submitted comments and proposed Board responses to those comments. Staff and Regulations Counsel recommend the Board approve the following proposed responses to the comments.

A. Consideration of Public Comments Received During the 15-Day Public Comment Period on Second Modified Text and Proposed Responses Thereto

In accordance with Government Code section 11346.9, subdivision (a)(3), the Board, in its Final Statement of Reasons supporting the rulemaking, must summarize each objection or recommendation and the reasons for making or not making a change. Summaries of the comments received and proposed responses developed by staff in consultation with Regulations Counsel are below for Board consideration and approval.

Comment from the California Academy of PAs (CAPA) - letter dated 03.20.24

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.

Comments from the California Medical Association (CMA) – letter dated 03.22.24

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 Business and Professions Code (BPC) section 3502 to establish "alternative mechanisms" for the adequate supervision of physician assistants by regulation. This was section 3 of the bill that repealed BPC section 3502(c)(3) (as previously enacted by Stats. 2015., ch. 536, § 2 (SB 337)), which previously read as follows:

> Notwithstanding any other law, the Medical Board of California or the board may establish other alternative mechanisms for the adequate supervision of the physician assistant.

Instead, BPC section 3502 now provides that "(a) Notwithstanding any other law, a PA may perform medical services as authorized by this chapter" if a specified list of requirements is 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 noted above, 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 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" at Attachment 4) 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 CMA's 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 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 section 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 section 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 1399.545(d) (renumbered as (b) in the Second Modified Text).

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.

Action Requested

Please review the attachments including the attached public comments, Second Modified Text in **Attachment 1**, the summary for each comment, the proposed responses to each comment, and the additional concerns and the rationales set forth above.

Proposed Motion Language – Response to Comments:

Motion A (If there are no changes to the proposed responses by members):

Direct staff to proceed as recommended to reject the comments as specified and provide the responses to the comments as indicated in the staff recommended responses.

Motion B (If there are changes to the proposed responses by members):

Direct staff to accept the following comment(s) and make the following edits to the text: [identify comment to accept and text to change here and explain why].

B. Consideration of Adoption of Amendments to CCR, Title 16, Sections 1399.502, 1399.540, 1399.541, and 1399.545 to Finalize the Current Rulemaking

Option A: If the Board rejects the previously discussed comments and makes no further changes to the proposed text, staff recommends the Board consider the following motion to complete the rulemaking process and adopt the proposed text:

Direct staff to take all steps necessary to complete the rulemaking process including the filing of the final rulemaking package with the Office of Administrative Law, authorize the Executive Officer to make any non-substantive changes to the proposed regulations and the rulemaking documents, and adopt the amendments to 16 CCR sections 1399.502, 1399.540, 1399.541, and 1399.545, as noticed in the Second Modified Text in **Attachment 1**.

Option B: If the Board disagrees or has further changes to the text, please entertain a motion to:

To approve the proposed modified regulatory text that includes the following changes to Attachment 1 [**describe amendments here**] and direct staff to take all steps necessary to complete the rulemaking process, including sending out modified text with these changes to **Attachment 1** for an additional 15-day comment period. If after the 15-day public comment period, the Board does not receive any objections or adverse recommendations specifically directed at the proposed action or to the procedures followed by the Board in proposing or adopting this action, authorize the Executive Officer to make any non-substantive changes to the proposed regulations, and adopt 16 CCR sections 1399.502, 1399.540, 1399.541, and 1399.545, as noticed in the Third Modified Text.

C. Consideration of Proposal to Authorize Initiation of a New Rulemaking to Amend CCR, Title 16, Sections 1399.502, 1399.540, 1399.541, and 1399.545

Under Government Code section 11346.4(b), the Board has one year from the date of the publication of the notice of proposed regulatory action to complete the rulemaking process. If the Board fails to meet this deadline, the Board must start over with a new filing if it would like to adopt regulations on this subject. The Board began the rulemaking process to implement SB 697 on July 28, 2023 and has until **Friday, July 26, 2024** to complete the rulemaking with the text approved above in Agenda Item 11.B. The Office of Administrative Law has thirty working days to complete its review of the Board's rulemaking file and proposed text (Gov. Code, § 11349.3).

In the unfortunate event that the Board runs out of time, staff are requesting that the Board authorize the Executive Officer to start the process over with the text in Attachment 5, which matches the text approved in Attachment 1 in the format required for beginning the rulemaking process.

If the Board has no changes to the Second Modified Text notice discussed in Item 11.B., staff request the Board move option A.

Option A: In the event that the Board is unable to complete the prior rulemaking implementing SB 697 in the time allotted by Government Code section 11346.4(b), approve the proposed regulatory text in **Attachment 5**, direct staff to submit the text to the Director of the Department of Consumer Affairs and the Business, Consumer Services, and Housing Agency for review. If the Board does not receive any objections or adverse recommendations specifically directed at the proposed action or to the procedures followed by the Board in proposing or adopting this action, authorize the Executive Officer to take all steps necessary to initiate the rulemaking process, make any non-substantive changes to the package, and set the matter for a hearing if requested. If no objections or adverse recommendations are received during the 45-day comment period and no hearing is requested, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at 16 CCR sections 1399.502, 1399.540, 1399.541, and 1399.545, as noticed.

Option B: If the Board disagrees or has further changes to the text, please entertain a motion to:

In the event that the Board is unable to complete the prior rulemaking implementing SB 697 in the time allotted by Government Code section 11346.4(b), approve the proposed regulatory text that includes the following changes to **Attachment 5** [**describe amendments here**] and, direct staff to submit the text to the Director of the Department of Consumer Affairs and the Business, Consumer Services, and Housing Agency for review. If the Board does not receive any objections or adverse recommendations specifically directed at the proposed action or to the procedures followed by the Board in proposing or adopting this action, authorize the Executive Officer to take all steps necessary to initiate the rulemaking process, make any non-substantive changes to the package, and set the matter for a hearing if requested. If after the 45-day public comment period, the Board does not receive any objections or adverse recommendations, authorize the Executive Officer to make any non-substantive changes to the proposed regulations, and adopt 16 CCR sections 1399.502, 1399.540, 1399.541, and 1399.545, as noticed.

Staff and Regulations Counsel will be available at the meeting to address any questions the Board may have. Please review the following attachments in preparation for discussion of this item at the meeting.

Attachment: 1. Second Modified Text
2. California Academy of PAs (CAPA) 03.20.24 comment letter
3. California Medical Association (CMA) 03.22.24 comment letter
4. Assembly Committee on Business and Professions Committee Analysis, SB 697 (Caballero), as Amended July 1, 2019
5. Originally Proposed Regulatory Text for Item C (to Re-Initiate a Rulemaking)

Attachment 1

DEPARTMENT OF CONSUMER AFFAIRS

Title 16. PHYSICIAN ASSISTANT BOARD

SECOND MODIFIED TEXT
SB 697 Implementation

Proposed amendments to the regulatory language are shown in single underline for new text and ~~single strikethrough~~ for deleted text.

Modifications to the proposed regulatory language are shown in double underline for new text and ~~double strikethrough~~ for deleted text.

Second modifications to the proposed ~~regulatory~~ language are shown in *italicized double underline* for new text and ~~*italicized double strikethrough*~~ for deleted text.

Amend Section 1399.502 of Article 1 of Division 13.8 of Title 16 of the California Code of Regulations

§1399.502 Definitions.

For the purposes of the regulations contained in this chapter, the terms

(a) "Board" means Physician Assistant Board.

(b) "Code" means the Business and Professions Code.

~~(c) "Physician assistant" means a person who is licensed by the board as a physician assistant.~~

~~(d) "Trainee" means a person enrolled and actively participating in an approved program of instruction for physician assistants.~~

(c~~e~~) "Approved program" means a program for the education and training of physician assistants which has been approved by the ~~b~~Board.

~~(f) "Supervising physician" and "physician supervisor" mean a physician licensed by the Medical Board of California or a physician licensed by the Osteopathic Medical Board of California.~~

(d~~g~~) "Approved controlled substance education course" means an educational course approved by the ~~b~~Board pursuant to section 1399.610.

(e) "Practice agreement" means the definition set forth in Section 3501(k) of the Code and it must contain the elements described in Section 3502.3 of the Code.

(f) "Supervision" means the definition set forth in Section 3501(f) of the Code.

NOTE: Authority cited: Section 3510, Business and Professions Code. Reference: Section 3510, Business and Professions Code.

Amend Section 1399.540 of Article 4 of Division 13.8 of Title 16 of the California Code of Regulations

§1399.540. Limitation on Medical Services.

~~*(a) A physician assistant may* only provide those medical services which he or she is competent to perform and which are consistent with the physician assistant's education, training, and experience, and which are delegated in writing by a supervising physician who is responsible for the patients cared for by that physician assistant. *provide those medical services which they are authorized to perform, which are consistent with the physician assistant's education, training, and experience, and which are rendered under the supervision of a licensed physician and surgeon pursuant to a practice agreement in accordance with Section 3502.3 of the Code.*~~

(~~*b*~~*a*) ~~The writing which delegates the medical services shall be known as a delegation of services agreement.~~ *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 ~~*or a 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)*~~. ~~each supervising physician. A delegation of services agreement may be signed by more than one supervising physician only if the same medical services have been delegated by each supervising physician. A physician assistant may provide medical services pursuant to more than one delegation of services agreement.~~

(~~*c*~~*b*) The ~~b~~Board or ~~Medical Board of California or their~~ its representative may require proof or demonstration of competence from any physician assistant for any tasks, procedures, or management ~~he or she is~~they are performing.

(~~*d*~~*c*) ~~A physician assistant shall consult with a physician regarding any task, procedure, or diagnostic problem which the physician assistant determines exceeds his or her level of competence or shall refer such cases to a physician.~~ ~~When a physician assistant determines~~If any task, procedure, or diagnostic problem exceeds the~~ir own~~ physician assistant's level of competence, they shall either consult a supervising physician and surgeon, or refer the patient to a physician and surgeon or licensed healthcare provider competent to render the services needed for the task, procedure, or diagnosis.

NOTE: Authority cited: Sections 2018, 3502 and 3510, Business and Professions Code. Reference: Section 3502, 3502.3, 3509, 3516 and 3527, Business and Professions

Amend Section 1399.541 of Article 4 of Division 13.8 of Title 16 of the California Code of Regulations

§1399.541. Medical Services Performable.

~~Because physician assistant practice is directed by a supervising physician, and a physician assistant acts as an agent for that physician, the orders given and tasks performed by a physician assistant shall be considered the same as if they had been~~

given and performed by the supervising physician. Unless otherwise specified in these regulations or in the delegation or protocols, these orders may be initiated without the prior patient specific order of the supervising physician.

A physician assistant may, pursuant to Section 3502 of the Code, initiate an order or

In any setting, including for example, any licensed health facility, out-patient settings, patients' residences, residential facility/ies, and hospices, as applicable, a physician assistant may, pursuant to a delegationpractice agreementand protocols where present:

(a) Take a patient history; perform a physical examination and make an assessment and diagnosis therefrom; initiate, review and revise treatment and therapy plans including plans for those services described in Section 1399.541(b) through Section 1399.541(ij) inclusive; and record and present pertinent data in a manner meaningful to the physician.

(b) Order or transmit an order for x-ray, other studies, therapeutic diets, physical therapy, occupational therapy, respiratory therapy, and nursing services.

(c) Order, transmit an order for, perform, or assist in the performance of laboratory procedures, screening procedures, and therapeutic procedures.

(d) Recognize and evaluate situations which call for immediate attention of a physician and institute, when necessary, treatment procedures essential for the life of the patient.

(e) Instruct and counsel patients regarding matters pertaining to their physical and mental health. Counseling may include topics such as medications, diets, social habits, family planning, normal growth and development, aging, and understanding of and long-term management of their diseases.

(f) Initiate arrangements for admissions, complete forms and charts pertinent to the patient's medical record, and provide services to patients requiring continuing care, including patients at home.

(g) Initiate and facilitate the referral of patients to the appropriate health facilities, agencies, and resources of the community.

(h) Administer or provide medication to a patient, or issue or transmit drug orders orally or in writing in accordance with the provisions of subdivisions (a)-(f), inclusive, of Section 3502.1 of the Code.

(i)(1) Perform*ance of* surgical procedures *without the personal presence of the*

local anesthesia or procedural sedation.
*Prior to a physician assistant performing*delegating any such *surgical procedures under*

~~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. All other s~~Surgical procedures ~~requiring other forms of~~ procedural

~~performed by a physician assistant only~~ when~~in the personal presence of a supervising~~

(2) A physician assistant may also act as first or second assistant in surgery ~~under the supervision of a supervising physician~~as authorized by the practice agreement and in accordance with the requirements of Section 3502 of the Code. ~~The physician assistant may so act without the personal presence of the supervising physician if the supervising physician is immediately available to the physician assistant. "~~Immediately available" means the physician is physically accessible and able to return to the patient, without any delay, upon the request of the physician assistant to address any situation requiring the supervising physician's services.

~~(3) "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.~~

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

~~(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*.

NOTE: Authority cited: Sections 2018, 3502 and 3510, Business and Professions Code. Reference: Sections 2058, 3501, 3502, ~~and~~ 3502.1, 3502.3 and 3509, Business and Professions Code.

Amend Section 1399.545 of Article 4 of Division 13.8 of Title 16 of the California Code of Regulations

§1399.545. Supervision Required.

(a) A supervising physician shall be available to receive inquiries~~, *in person,*~~ by telephone, or by other electronic communication ~~at all times~~ when the physician assistant is ~~caring~~providing medical services for patients.

~~(b) A supervising physician shall delegate to a physician assistant only those tasks and procedures consistent with the supervising physician's specialty or usual and customary practice and with the patient's health and condition.~~

~~(c) A supervising physician shall observe or review evidence of the physician assistant's performance of all tasks and procedures to be delegated to the physician assistant until assured of competency.~~

~~*(db) The physician assistant and the supervising physician*~~*practice agreement shall ~~establish in writing transport and back-up procedures for the immediate care of patients~~*

~~*who are in need of emergency care beyond the physician assistant's scope of practice for such times when a supervising physician is not on the premises*~~*training and comptency*~~.~~

~~(e) A physician assistant and his or her supervising physician shall establish in writing guidelines for the adequate supervision of the physician assistant which shall include one or more of the following mechanisms:~~

~~(1) Examination of the patient by a supervising physician the same day as care is given by the physician assistant;~~

~~(2) Countersignature and dating of all medical records written by the physician assistant within thirty (30) days that the care was given by the physician assistant;~~

~~(3) The supervising physician may adopt protocols to govern the performance of a physician assistant for some or all tasks. The minimum content for a protocol governing diagnosis and management as referred to in this section shall include the presence or absence of symptoms, signs, and other data necessary to establish a diagnosis or assessment, any appropriate tests or studies to order, drugs to recommend to the patient, and education to be given the patient. For protocols governing procedures, the protocol shall state the information to be given the patient, the nature of the consent to be obtained from the patient, the preparation and technique of the procedure, and the follow-up care. Protocols shall be developed by the physician, adopted from, or referenced to, texts or other sources. Protocols shall be signed and dated by the supervising physician and the physician assistant. The supervising physician shall review, countersign, and date a minimum of 5% sample of medical records of patients treated by the physician assistant functioning under these protocols within thirty (30) days. The physician shall select for review those cases which by diagnosis, problem, treatment or procedure represent, in his or her judgment, the most significant risk to the patient;~~

~~(4) Other mechanisms approved in advance by the board.~~

(~~fc~~b) The supervising physician has continuing responsibility to follow the progress of the patient and to make sure that the physician assistant does not function ~~autonomously~~ without supervision. The supervising physician shall be responsible for all medical services provided by a physician assistant under ~~his or her~~their supervision.

NOTE: Authority cited: Sections 2018, 3502, 3502.3 and 3510, Business and Professions Code. Reference: Sections 3501, 3502, 3502.3 and 3516, Business and Professions Code.

Attachment 2

March 20, 2024

The Honorable Sonya Early
President, Physician Assistant Board
Hon. Board Members
2005 Evergreen Street, Suite 2250
Sacramento, CA 95815

The Honorable Rozana Khan
Executive Officer,
Physician Assistant Board
2005 Evergreen Street, Suite 2250
Sacramento, CA 95815

Ms. Jasmine Dhillon
Legislative and Regulatory Specialist,
Physician Assistant Board
2005 Evergreen Street, Suite 2250
Sacramento, CA 95815
Email Address: jasmine.dhillon@dca.ca.gov

RE: CAPA Comment on Proposed Regulatory Language dated March 7, 2024, to Implement Senate Bill No. 697 (2019, Caballero)

Dear President Early and Honorable Board Members, Executive Officer Khan, and Specialist Dhillon:

On behalf of the 14,000 physician assistants (PAs) licensed in California, the California Academy of PAs (CAPA) is pleased to offer its enthusiastic support to the proposed regulatory language by the Physician Assistant Board (PAB) released March 7, 2024.

The PAB Properly and Lawfully Implements Senate Bill No. 697 in its Proposed Amendments to Section 1399.540 of Article 4 of Division 13.8 of Title 16 of the California Code of Regulations

We commend the PAB for its proposed amendments to this Section[1], which correctly implement the legislative intent of SB 697. The PAB has proposed the following revised amendments to Section 1399.540:

[1] All "section" references are to the sections of the regulations.

~~(a) A physician assistant may only provide those medical services which he or she is competent to perform and which are consistent with the physician assistant's education, training, and experience, and which are delegated in writing by a supervising physician who is responsible for the patients cared for by that physician assistant.~~ ~~provide those medical services which they are authorized to perform, which are consistent with the physician assistant's education, training, and experience, and which are rendered under the supervision of a licensed physician and surgeon pursuant to a practice agreement in accordance with Section 3502.3 of the Code.~~

(~~b~~a) ~~The writing which delegates the medical services shall be known as a delegation of services agreement.~~ 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 ~~or a 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)~~. ~~each supervising physician. A delegation of services agreement may be signed by more than one supervising physician only if the same medical services have been delegated by each supervising physician. A physician assistant may provide medical services pursuant to more than one delegation of services agreement.~~

(~~c~~b) The ~~b~~Board or ~~Medical Board of California or their~~ its representative may require proof or demonstration of competence from any physician assistant for any tasks, procedures, or management ~~he or she is~~they are performing.

(~~d~~c) ~~A physician assistant shall consult with a physician regarding any task, procedure, or diagnostic problem which the physician assistant determines exceeds his or her level of competence or shall refer such cases to a physician.~~ ~~When a physician assistant determines~~If any task, procedure, or diagnostic problem exceeds the~~ir own~~ physician assistant's level of competence, they shall either consult a supervising physician and surgeon, or refer the patient to a physician and surgeon or licensed healthcare provider competent to render the services needed for the task, procedure, or diagnosis.

COMMENT: These amendments are required to ensure the regulation does not contradict binding statute. As the PAB staff correctly observes its Initial Statement of Reasons dated May 16, 2023, these changes are necessary to Section 1399.540 because it references an outdated model of services being "delegated," and it conflicts with statutes establishing a PA's right to practice as authorized and memorialized in a practice agreement.

First, prior to the enactment of SB 697, PAs operated under a "delegated services agreement" and "protocols." SB 697 repealed those references. Hence, all the regulation's references to "delegation of services agreements" and what must be contained in them must likewise be repealed. (See, e.g., former Business & Professions Code (BPC) section 3501, 3502(c), 3502.1).

Second, the current regulation's first sentence of (d) ("A physician assistant shall consult …) conflicts with BPC section 3502.3, which states:

> 3502.3. (a) (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.
(C) The methods for the continuing evaluation of the competency and qualifications of the physician assistant.
(D) The furnishing or ordering of drugs or devices by a physician assistant pursuant to Section 3502.1.
(E) Any additional provisions agreed to by the physician assistant and physician and surgeon.

The PAB correctly recognizes that this first sentence of (d) of the current regulations which dictates "consultations" conflicts with statute. Pursuant to BPC section 3502.3(a)(1)(B), the practice agreement must address consultations and referrals, thus exclusively reposing the when and wherefores of referrals to practice agreements. As the current regulation dictating when "consultations" and "referrals" must occur is inconsistent with that issue being addressed dispositively by the parties to the practice agreement, the regulation is inconsistent with binding law and must be repealed, as proposed.

More broadly, as observed by Former PAB President Grant at the August 7, 2020, meeting, at p. 21 of the minutes, PA practice is now authorized by the contents of practice agreements. As the PAB staff correctly explained in the August 7, 2020, board materials at p. 74: "The new law instead authorizes a physician assistant to perform medical services authorized by the Act if certain requirements are met, including that the medical services are rendered pursuant to a practice agreement, as defined and the physician assistant is competent to perform the medical services." After SB 697, the PAB is without statutory authority to step into the shoes of one of the parties to practice agreements and write them.

Moreover, this "consultation" language was written under the model of an individual physician delegating their authority to an individual physician assistant on a task-by-task basis, who, absent that delegation, lacked their own medical authority. This is no longer the law.

Further, a real-life example illustrates how the regulation dictating when "consultations" and "referrals" must occur is inconsistent with SB 697 reposing those very questions to the practice agreement parties. In real-life applications within an integrated health care system, a practice agreement may require a PA to refer a patient to someone who is not, as is currently required, a physician. The agreement could require referral to a podiatrist or to a dentist or to mental health provider, depending upon the patient and the practice. The same is true with consultations. Thus, because the practice agreement can legally authorize the PA to refer to other licensed healthcare providers, the modified regulation properly reflects the breath of current law by proposing to delete contrary language.

In its memorandum dated January 29, 2024, the PAB also accurately states that the regulatory language in subdivision (a) and part of subdivision (b), simply restate BPC section 3502.3 requirements and do not clarify BPC section 3502.3 further.[2] The PAB is correct, and in its proposed changes it corrects these errors and aligns the regulation with binding statute.

[2] https://www.pab.ca.gov/about_us/meetings/materials/20240304_12.pdf

Furthermore, removal of subdivision (a) and proposed revisions to subdivision (b) align with the enabling statute that the PA is authorized to perform services through the practice agreement. The language that only repeats that of the enabling statute is stricken.

The PAB Properly and Lawfully Implements Senate Bill No. 697 in its Proposed Amendments to Section 1399.541 of Article 4 of Division 13.8 of Title 16 of the California Code of Regulations

We commend the PAB for its proposed amendments to this Section, which correctly implement the legislative intent of Senate Bill No. 697. The PAB has proposed the following revised amendments, dated March 7, 2024:

> ~~Because physician assistant practice is directed by a supervising physician, and a physician assistant acts as an agent for that physician, the orders given and tasks performed by a physician assistant shall be considered the same as if they had been given and performed by the supervising physician. Unless otherwise specified in these regulations or in the delegation or protocols, these orders may be initiated without the prior patient specific order of the supervising physician.~~
> ~~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.~~
>
> In any setting, including for example, any licensed health facility, out-patient settings, patients' residences, residential facility~~ies~~, and hospice~~s~~, as applicable, a physician assistant may, pursuant to a ~~delegation~~practice agreement~~and protocols where present~~:
> (a) Take a patient history; perform a physical examination and make an assessment and diagnosis therefrom; initiate, review and revise treatment and therapy plans including plans for those services described in Section 1399.541(b) through Section 1399.541(~~i~~j) inclusive; and record and present pertinent data in a manner meaningful to the physician.
> (b) Order or transmit an order for x-ray, other studies, therapeutic diets, physical therapy,
> occupational therapy, respiratory therapy, and nursing services.
> (c) Order, transmit an order for, perform, or assist in the performance of laboratory procedures, screening procedures, and therapeutic procedures.
> (d) Recognize and evaluate situations which call for immediate attention of a physician and institute, when necessary, treatment procedures essential for the life of the patient.
> (e) Instruct and counsel patients regarding matters pertaining to their physical and mental health. Counseling may include topics such as medications, diets, social habits, family planning, normal growth and development, aging, and understanding of and long-term management of their diseases.
> (f) Initiate arrangements for admissions, complete forms and charts pertinent to the patient's medical record, and provide services to patients requiring continuing care, including patients at home.
> (g) Initiate and facilitate the referral of patients to the appropriate health facilities, agencies, and resources of the community.

(h) Administer or provide medication to a patient, or issue or transmit drug orders orally or in writing in accordance with the provisions of subdivisions (a)-(f), inclusive, of Section
3502.1 of the Code.

(i)(1) Perform~~ance of~~ surgical procedures ~~without the personal presence of the supervising physician.~~as authorized by the practice agreement and in accordance with the requirements of Section 3502 of the Code. ~~Perform surgical procedures without the personal presence of the supervising physician which are customarily performed under local anesthesia or procedural sedation. Prior to a physician assistant performing~~delegating any such ~~surgical procedures under local anesthesia, or sedation other than local anesthesia, including procedural sedation, or general anesthesia, the physician assistant shall ensure the supervising physician shall reviews the evidence~~documentation ~~which indicates that the physician assistant is trained and qualified to perform the surgical procedures under such sedation. 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. All other s~~Surgical procedures requiring ~~other forms of procedural sedation or sedation other than local anesthesia, including general anesthesia may be performed by a physician assistant only when~~in the personal presence of a ~~supervising physician is immediately available during the procedure.~~

(2) A physician assistant may also act as first or second assistant in surgery ~~under the supervision of a supervising physician~~as authorized by the practice agreement and in accordance with the requirements of Section 3502 of the Code. ~~The physician assistant may so act without the personal presence of the supervising physician if the supervising physician is immediately available to the physician assistant.~~ ~~"Immediately available" means the physician is physically accessible and able to return to the patient, without any delay, upon the request of the physician assistant to address any situation requiring the supervising physician's services.~~

~~(3) "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.~~

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

(~~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.

COMMENT: The PAB notes in its Initial Statement of Reasons dated May 16, 2023, the existing first paragraph conflicts with BPC section 3502.3. The conflict arises in that PA practice is not "directed" by a supervising physician – rather, it is "authorized." Furthermore, section 3502.3 (a)(4) makes it clear that a practice agreement "may" designate a PA as an agent, but it need not do so. In unlawful contrast, the regulation deems a PA always to be an "agent." In its memorandum dated January 29, 2024, the PAB accurately restated that the introductory paragraph to Section 1399.541 is unnecessary and superseded by enabling statute.

The PAB initially proposed changes to the subdivision requiring a specific level of supervision during surgical procedures. But, in its memorandum dated January 29, 2024, p. 4, the PAB staff accurately states:

> 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.

PAB staff is correct.

First, as previously drafted, the proposed regulation conflicts with state law. BPC section 3501(f)(1) states that "supervision… ***shall not be construed to require the physical presence of the physician and surgeon***" (Emphasis added). The previous proposed regulation was unlawful and flatly inconsistent with the enabling statute, in that it mandates a PA may perform procedures requiring anesthesia "only in the ***personal presence*** of a supervising physician." (Emphasis added). As the PAB Regulations Counsel correctly stated at the PAB hearing on March 4, 2024, requiring a supervising physician to be "physically accessible" is equivalent to requiring a form of "physical presence" of the supervising physician – which is expressly prohibited by the enabling statute.

Second, and more broadly, the only requirement in current law applicable to this situation is that a PA must be in some manner "supervised" by a physician and surgeon with the exact contours of that supervision to be decided in a practice agreement. In contradiction, the prior proposal unambiguously requires a particular kind of supervision when the topic is, by the plain language of the statute, exclusively reposed to the parties in practice agreements. Under current law, the level of supervision is exclusively reposed to the parties in the practice agreement. If the PAB sought to enforce this requirement, it would likely end-up having to defend it in court and the PAB would not likely prevail.

Except for those enumerated restrictions on PA practice set forth in BPC section 3502 which cannot be waived or altered by practice agreements, all other matters relating to the relationship between the physician and surgeon and the PA – including supervision – are now exclusively a matter between the parties to a practice agreement. BPC Section 3502, which establishes a PA's right to practice, with emphasis added, reads in 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 ...

The statute begins, "[n]otwithstanding any other law." This means no other statute or regulation can contradict it. This is what SB 697 was, in fact, all about:

> [T]his 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.

Assembly Business & Professions Committee analysis and explanation of SB 697, July 9, 2019,
p. 5 (emphasis supplied).[3] In the PAB's proposed language to subdivision (i), the regulation lawfully implements the legislative intent for practices to determine what level of supervision for surgical procedures is appropriate.

A former PAB President at the PAB's hearing on March 4, 2024, argued the PAB should set standards on the degree of supervision required for patients under general anesthesia, requiring the immediate availability for the personal presence of the supervising physician. Respectfully, this is neither lawful nor consistent with best medical practices, for the following reasons:

First, as discussed, it is the medical professionals under SB 697 who know their competencies, their experiences, and the needs of their patients who are qualified on a case-by-case basis who are best situated to determine supervision. The PAB is not. As described above, SB 697 reposes these questions to those qualified to render them. There is no statutory foothold for the PAB to intervene.

Second, the regulation specified surgical settings when the statute makes no distinction and thus allowance for such a carve-out unique to just one setting.

Third, the proposed changes released December 5, 2023, in effect, flipped the legally established relationship between PAs and supervising physicians and surgeons upside down. The proposed regulations do this by requiring a PA somehow to "ensure" – guarantee – a physician and surgeon "reviews evidence" of the PA's procedural-related training and qualifications prior to a PA performing a surgical procedure and conducts their own assessment of the patient prior to a PA performing a surgical procedure. A regulatory proposal that mandates that a PA "ensure" that a physician and surgeon do anything, including reviewing the training and qualification of PAs and conducting patient assessments, is unlawful. Not only is there no statutory authority that would lawfully enable a PA to insist or instruct physicians and surgeons to do things as the plain text of current law establishes a physician and surgeon supervisorial relationship with PAs through practice agreements, contradicting this proposal. In its memorandum dated January 29, 2024, the PAB agreed that these reviews and assessments are determined at the practice level in the practice agreement, striking the previously proposed language.

Fourth, the proposed changes released December 5, 2023, simply do not reflect an understanding of anesthesia. The proposed regulations confusingly depart from standard medical practice and terminology, by defining "sedation other than local anesthesia," which "includes general anesthesia." It subverts the prevailing consensus from both Center for Medicare & Medicaid Services and the American Society of Anesthesiologist as it relates to commonly understand definitions of local anesthesia, procedural sedation, and general anesthesia. That the proposed regulations get this medical issue wrong provides further

[3] https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201920200SB697

evidence as to why SB 697 leaves practice-level decisions to the physician assistant and supervising physician and surgeon to determine.

Fifth, the former President (with whom we worked productively on these issues and whose leadership in implementing SB 697 is to be applauded) referenced in the March hearing that the language regarding surgical supervision was "bargained." But, in our July, 2021 letter we maintained that SB 697 states in clear language that supervision "shall not be construed to require the physical presence of the physician and surgeon." While we also thereafter expressed appreciation to the PAB for attempting to address our concerns in a "balanced" way, this gesture of appreciation to our regulator should not, with respect, be construed as a bargain and, in any event, no bargain can overcome the fact that the requirement, as staff points out correctly, directly contradicts superior statute.

Lastly, proposed subdivision (j) was not necessary for the implementation of SB 697. In its memorandum dated January 29, 2024, the PAB expressed concerns that the proposed language does not capture the correct "informed consent" standard and therefore is not reflective of current practice. In addition to those concerns, the proposal violates BPC Section 3502, in that it is up to physician and surgeons to interpret the legal requirements of informed consent and operationalize those requirements is a matter reposed to their professional judgements as memorialized in the practice agreement. The PAB is correct to remove this language from the proposed rulemaking.

The PAB Properly and Lawfully Implements Senate Bill No. 697 in its Proposed Amendments to Section 1399.545 of Article 4 of Division 13.8 of Title 16 of the California Code of Regulations

We commend the PAB for its proposed amendments to this Section, which correctly implement the legislative intent of Senate Bill No. 697. The PAB has proposed the following revised amendments, dated March 7, 2024:

> (a) A supervising physician shall be available to receive inquiries~~, in person,~~ by telephone,
> or by other electronic communication ~~at all times~~ when the physician assistant is ~~caring~~providing medical services for patients.
> ~~(b) A supervising physician shall delegate to a physician assistant only those tasks and procedures consistent with the supervising physician's specialty or usual and customary practice and with the patient's health and condition.~~
> ~~(c) A supervising physician shall observe or review evidence of the physician assistant's performance of all tasks and procedures to be delegated to the physician assistant until assured of competency.~~
> ~~(db) The physician assistant and the supervising physicianpractice agreement shall establish in writing transport and back-up procedures for the immediate care of patients who are in need of emergency care beyond the physician assistant's scope of practice for such times when a supervising physician is not on the premisestraining and comptency.~~
> ~~(e) A physician assistant and his or her supervising physician shall establish in writing guidelines for the adequate supervision of the physician assistant which shall include one or more of the following mechanisms:~~

~~(1) Examination of the patient by a supervising physician the same day as care is given by the physician assistant;~~
~~(2) Countersignature and dating of all medical records written by the physician assistant within thirty (30) days that the care was given by the physician assistant;~~
~~(3) The supervising physician may adopt protocols to govern the performance of a physician assistant for some or all tasks. The minimum content for a protocol governing diagnosis and management as referred to in this section shall include the presence or absence of symptoms, signs, and other data necessary to establish a diagnosis or assessment, any appropriate tests or studies to order, drugs to recommend to the patient, and education to be given the patient. For protocols governing procedures, the protocol shall state the information to be given the patient, the nature of the consent to be obtained from the patient, the preparation and technique of the procedure, and the follow-up care. Protocols shall be developed by the physician, adopted from, or referenced to, texts or other sources. Protocols shall be signed and dated by the supervising physician and the physician assistant. The supervising physician shall review, countersign, and date a minimum of 5% sample of medical records of patients treated by the physician assistant functioning under these protocols within thirty (30) days. The physician shall select for review those cases which by diagnosis, problem, treatment or procedure represent, in his or her judgment, the most significant risk to the patient;~~
~~(4) Other mechanisms approved in advance by the board.~~
(~~f~~cb) The supervising physician has continuing responsibility to follow the progress of the patient and to make sure that the physician assistant does not function ~~autonomously~~ without supervision. The supervising physician shall be responsible for all medical services provided by a physician assistant under ~~his or her~~their supervision

COMMENT: The PAB notes in its Initial Statement of Reasons dated May 16, 2023, that changes are necessary to remove subdivision (b) because the PA's authority to perform medical services is addressed in statute, and to remove subdivision (c) because it conflicts with the statute. The PAB is correct on this point. BPC section 3502 states (emphasis added):

(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 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***.

Therefore, because BPC section 3502 outlines the services that the physician assistant can perform, all of current subdivision (b) directly contradicts that intent and is unlawful. As previously noted, because services are "authorized" and not "delegated", subdivision (c) is also unlawful and requires amendment.

In its memorandum dated January 29, 2024, the PAB staff correctly recommends deletion of subdivision (d) in its entirety 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." BPC 3502.3 outlines the contents of the practice agreement and does not include "written transport and back-up procedures" as a required component.

The PAB also correctly observes that subdivision (e) must be removed, as it conflicts with the enabling statute. BPC Section 3502(c) states "Nothing in regulations shall require that a physician and surgeon review or countersign a medical record of a patient treated by a physician assistant, unless required by the practice agreement." Therefore, regulations in subdivision (e) were unlawful as they suggested the following guidelines: "***Countersignature*** and dating of all medical records" or "The supervising physician shall review, ***countersign***, and date a minimum of 5% sample of medical records" (Emphasis added). The PAB's proposed removal of this subdivision is necessary to implement the intent of SB 697.

Conclusion

Given that it has taken over three years to enact regulations necessary to implement Senate Bill No. 697, CAPA applauds the PAB for their commitment to work in finalizing the rulemaking process. The proposed regulatory language revisions dated March 7, 2024, accurately implement the plain language and legislative intent of SB 697

With gratitude for the opportunity to support the proposed regulations and with the hope that CAPA and the PAB will always continue their collaboration on these matters of intense interest to patients, PAs, physicians and surgeons, and the Legislature, I remain

Very truly yours,

Scott Martin, PA-C
CAPA President

Attachment 3

CALIFORNIA MEDICAL ASSOCIATION

March 22, 2024

Jasmine Dhillon
Physician Assistant Board Office
2005 Evergreen Street, Suite 2250
Sacramento, CA 95815-3893

Sent via email to jasmine.dhillon@dca.ca.gov

Re: SB 697 Implementation Rulemaking, Second Modified Text of Proposed Regulations

Dear Ms. Dhillon:

On behalf of our nearly 50,000 physician and medical student members, the California Medical Association (CMA) thanks the Physician Assistant Board (PAB) for considering our comments on the second modified text of the proposed SB 697 Implementation Rulemaking.

We appreciate the Board's efforts and diligence in developing the proposed regulations. We offer the following additional comments to further the common goals of patient safety and consumer protection, consistent with the requirements of SB 697 (Stats. 2019, Ch. 707).

I. 1399.541(i)(1): Supervising Physician Review of Physician Assistant's Training and Qualifications Before Surgical Procedures under Sedation

The second modified text of the proposed regulations deleted language in 16 CCR § 1399.541(i)(1) that required a physician assistant (PA) to ensure a supervising physician reviews a PA's training and qualification to perform a surgical procedure under sedation prior to surgery. The Board made this change in response to comments regarding the lack of authority by a PA to "ensure" or otherwise compel a supervising physician to undertake an action, as well as an argument from a stakeholder that any such requirement is inconsistent with Business and Professions Code (BPC) section 3502(a).

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. CMA proposed revisions in our December 20, 2023 comment letter to clarify that the physician must review the PA's training instead.

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. A practice agreement (BPC § 3502(a)(2)) is one of *four* criteria that must be met under section 3502(a). Other criteria include, in relevant part, the PA's "competen[cy] to perform the services" (§ 3502(a)(3)) and "education, training, and experience

… to render the services" (§ 3502(a)(4)). 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, it is appropriate to reiterate that in the implementing regulations by requiring supervising physicians to confirm a PA meets those requirements.

CMA also proposes to clarify the previous drafting regarding sedation, local anesthesia, and general anesthesia to avoid potential structural ambiguities.

Accordingly, CMA urges the Board to add the following language in § 1399.541(i)(1):

> 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.***

II. 1399.541(i)(1), (2) & (3): Immediate Availability of Supervising Physician during Surgical Procedures under Sedation by Physician Assistant

The second modified text deleted 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. A definition of "immediately available" in paragraph (i)(3) was also accordingly deleted. The Board made this change in response to an argument from a stakeholder that BPC sections 3502 and 3502.3 do not carve out surgical procedures under anesthesia or sedation for special treatment.

While the statutes do not expressly impose any specific requirements for PAs performing surgical procedures under anesthesia or sedation, they repeatedly impose requirements concerning a PA's competency and qualifications both in general (BPC § 3502.3(a)(1)(B)) and specific to the services being rendered (BPC § 3502(a)(3) & (4)). Section 3502.3(a)(1) also requires a practice agreement between a supervising physician and PA to address, in part:

> (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.
>
> (C) The methods for the continuing evaluation of the competency and qualifications of the physician assistant.

As discussed above, performing surgical procedures under anesthesia or sedation carries heightened risks to patient safety. Accordingly, it is appropriate for the 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:

> ***(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.***

III. 1399.545(b): Procedures for Immediate Care of Patients in Emergencies Beyond PA's Training and Competency

The second modified text deleted § 1399.545(b) 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. The Board made this change "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." PAB Memorandum, p. 8 (Jan. 29, 2024).

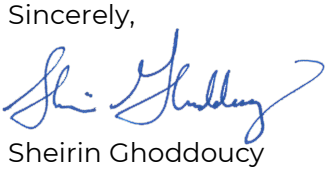
As discussed above, BPC 3502.3 requires practice agreements to address, in part, "**[p]olicies and procedures** to ensure adequate supervision of the physician assistant, including, but not limited to, appropriate communication, availability, consultations, and referrals between a physician and surgeon 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).) 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, 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 in § 1399.5(b):

(b) The practice agreement shall establish procedures for the immediate care of patients who are in need of emergency care beyond the physician assistant's training and competency.

Thank you for your consideration of CMA's comments. We look forward to working with the Board to further its goal of ensuring the protection of public health and supporting the betterment of the medical profession. If any further information or clarification is needed, please do not hesitate to contact me at sghoddoucy@cmadocs.org.

Sincerely,



Sheirin Ghoddoucy
Senior Legal Counsel
California Medical Association

Attachment 4

Date of Hearing: July 9, 2019

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
SB 697 (Caballero) – As Amended July 1, 2019

SENATE VOTE: 37-0

SUBJECT: Physician assistants: practice agreement: supervision

SUMMARY: Revises the way physician assistants are supervised by physicians, allowing multiple physicians and surgeons to supervise a physician assistant (PA); redefines the supervision agreement, called a delegation of services agreement (DSA), as a practice agreement; eliminates the statutory requirement of medical records review; generally allows supervising physician and surgeons to determine the appropriate level of supervision for PA practice; and makes other conforming and technical changes.

EXISTING LAW:

1) Regulates and licenses PAs under the Physician Assistant Practice Act. (Business and Professions Code (BPC) §§ 3500-3546)

2) Establishes, until January 1, 20201, the Physician Assistant Board (PAB) to administer and enforce the PA Practice Act. (BPC § 3504)

3) Defines a DSA as the writing that delegates to a PA from a supervising physician the medical services the PA is authorized to perform. (BPC § 3501(a)(10))

4) Specifies that that a PA acts as an agent of the supervising physician when performing any activity authorized by the Act. (BPC § 3501(b))

5) Authorizes a PA to perform medical services under the supervision of a physician and surgeon who must be physically available to the PA. (BPC § 3502(a)(2))

6) Requires the PA and the PA's supervising physician and surgeon to establish written guidelines for adequate supervision and adhere to specific medical records review processes. (BPC § 3502(c))

7) Authorizes a supervising physician and surgeon to delegate the authority to issue a drug order to a PA, and may limit this authority by specifying the manner in which the PA may issue delegated prescriptions by adopting a formulary and protocols that specify all criteria for the use of a particular drug or device. The drugs listed in the protocols must constitute the formulary and shall include only drugs that are appropriate for use in the type of practice engaged in by the supervising physician and surgeon. When issuing a drug order, the PA is acting on behalf of and as an agent for a supervising physician and surgeon. (BPC § 3502.1(a))

8) Authorizes a nurse practitioner to furnish or order drugs or devices when operating in accordance with standardized protocols developed by the nurse practitioner and supervising physician. (BPC § 2836.1)

9) Specifies that "supervision", as it relates to nurse practitioners and certified nurse-midwives, shall not be construed to require the physical presence of the physician, but does include collaboration on the development of the standardized procedure, approval of the standardized procedure, and availability by telephonic contact at the time of patient examination by the NP. (BPC §§ 2746.5, 2746.51, 2831(d))

THIS BILL:

1) Provides that "supervision" is not meant to require the physical presence of the physician and surgeon.

2) Defines "regulations" as the rules and regulations as set forth by the PAB, as those provisions read on June 7, 2019.

3) (8) (h) "Rou

4) Defines an "organized health care system" to include a licensed clinic, an outpatient setting, a health facility, a county medical facility, an accountable care organization, a home health agency, a physician's officer, a professional medical corporation, a medical partnership, a medical foundation, and any other organized entity that lawfully provides medical services, as specified.

5) Strikes references to a DSA and replaces it with "practice agreement," which means the writing, developed through collaboration among one or more physicians and surgeons, one or more PAs, and, if applicable, administrators of an organized health care system, that outlines the medical services the PA is authorized to perform and that grants approval for physicians and surgeons to supervise one or more PAs. States that any reference to a DSA relating to PAs in any other law shall have the same meaning as a practice agreement.

6) Deletes the definition of and references to a "medical records review meeting."

7) Strikes references to the requirement that each medical record, for each episode of patient care, identifies the physician and surgeon responsible for the supervision of the PA.

8) Deletes the provision of law stating that a PA acts as an agent of the supervising physician when performing activities authorized under the PA Practice Act.

9) Authorizes a PA to perform medical services under the PA Practice act if the PA meets the following requirements:

   a) 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 MBC or by the Osteopathic Medical Board prohibiting that supervision or prohibiting the employment of a PA.

   b) The PA renders the services pursuant to a practice agreement.

c) The PA is competent to perform the services.

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

10) Strikes references to a supervising physician and surgeon adopting written guidelines for some or all of the tasks performed by the PA.

11) Specifies that the PA Practice Act may not be construed to require a physician to review or countersign a patient's medical record who was treated by a PA, unless required by the practice agreement. The PAB may, as a condition of probation of a licensee, require the review or countersignature of records of patients treated by a PA for a specified duration.

12) Redrafts provisions of law relating to PAs furnishing or ordering drugs and devices in context of the practice agreement.

13) Authorizes a PA to furnish or order a drug or device in accordance with the practice agreement and consistent with the PA's educational preparation or for which clinical competency has been established and maintained.

14) Requires a practice agreement to include the following:

a) The types of medical services a PA is authorized to perform and how the services are performed.

b) Policies and procedures to ensure adequate supervision of the PA, including but not limited to, appropriate communication, availability, consultations, and referrals between a physician and surgeon and the PA in the provision of medical services.

c) The methods for the continuing evaluation of the PA's competency and qualifications.

d) The furnishing or ordering of drugs or devices by a PA.

e) Any additional provisions agreed to by the PA and physician and surgeon or organized health care system.

15) Requires the practice agreement to be signed by both the PA and one or more physicians and surgeons or a physician and surgeon who is authorized to approve the practice agreement on behalf of the staff of the physicians and surgeons on the staff of an organized health care system.

16) Deems a DSA in effect prior to January 1, 2020 to meet the requirements of this bill.

17) Specifies that the requirements under this bill may not be construed to require the PAB's approval of a practice agreement.

18) Deletes provisions of law that conflict with the principle of multiple physician and surgeon supervision of a PA.

19) Deletes outdated sections of code relating to the requirement that a supervising physician and surgeon apply to the PAB and pay a fee.

20) Makes technical and conforming changes.

FISCAL EFFECT: According to the Senate Appropriations Committee analysis of the April 24, 2019, version of this bill:

- No anticipated impact to the Physician Assistant Board (PAB) and the Medical Board.
- The Department of Consumer Affairs' Office of Information Services identified a fiscal impact of $54,000 to be funded through the redirection of existing maintenance resources. If regulations are required, and they impact IT work, IT requirements cannot be finalized until the regulations are completed.

COMMENTS:

Purpose. This bill is sponsored by the *California Academy of PAs*. According to the author, "There are several disparities between PAs and other medical professionals in the same arena when it comes to the relationship between PA and physician. In practice, this means PAs are subject to burdensome regulations such as chart review, co signatures, DSA requirements, and outdated ratios. These regulations incur a burden upon the physician as well, who may not be incentivized to hire a PA if a less regulated Nurse Practitioner is available. It is very possible that this disincentive to hire PAs may be contributing to the lack of healthcare services across out state, but especially in rural areas. To combat this distinction, regulations need to be revised for PAs to better match a Nurse Practitioner's status. That way, with added flexibility in the working relationship between physician and PA, PAs could be better utilized by physicians in areas where health care services are lacking. [This bill] seeks to reduce the burdens on the physician – PA relationship so practices can thrive and potentially expand."

Background. According to the PAB, a PA, is a licensed and highly skilled health care professional. PAs are trained academically and clinically to provide health care services with the direction and responsible supervision of a physician and surgeon. Within the physician-PA relationship, PAs make clinical decisions and provide a broad range of diagnostic, therapeutic, preventive, and health maintenance services.

The PA Practice Act has been updated several times over the decades to reflect changing realities in supervisory requirements and healthcare practices. However, according to the PAB and sponsors, the central concept of the PA practice, the close supervisorial relationship between a PA and a physician and surgeon remains essential to PA practice.

To become licensed in California, a PA must attend and graduate from an accredited PA program associated with a medical school that includes classroom studies and clinical experience. The professional curriculum for PA education includes basic medical, behavioral, and social sciences; introduction to clinical medicine and patient assessment; supervised clinical practice; and health policy and professional practice issues.

PA Scope and Supervision. A PA is authorized to perform many of the same diagnostic, preventative, and health maintenance services as a physician. Under current law, these services are authorized under a contractual and statutory agreement called a delegation of services agreement (DSA). The DSA outlines everything the PA is allowed to do. In establishing a DSA, a supervising physician uses professional and clinical judgment to review the PAs competency to perform a variety of services.

These services include, but are not limited to, the following:

- Taking health histories
- Performing physical examinations
- Ordering X-rays and laboratory tests
- Ordering respiratory, occupational, or physical therapy treatments
- Performing routine diagnostic tests
- Establishing diagnoses
- Treating and managing patient health problems
- Administering immunizations and injections
- Instructing and counseling patients
- Providing continuing care to patients in the home, hospital, or extended care facility
- Providing referrals within the health care system
- Performing minor surgery
- Providing preventative health care services
- Acting as first or second assistants during surgery
- Responding to life-threatening emergencies

In making the determination as to what a PA is allowed to perform, the physician also establishes case review and other requirements to ensure proper oversight. While there are statutory requirements as to the number of case reviews and other protections that a physician must meet, the 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.

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 in to 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.

ARGUMENTS IN SUPPORT:

The *California Academy of PAs* (sponsor) writes, "By enhancing the flexibility of healthcare teams at the practice level, responsiveness to local patients' needs will be significantly improved."

"It is not the intent of California PAs to expand their scope of practice nor to attempt to practice independently. Neither is there a desire to eliminate a medical practice's authority to supervise the PA. The goal of [this bill] is to allow the PA to work more effectively within the four walls of the practice by removing redundant and outmoded administrative constraints."

America's Physician Groups writes, "We have worked with the bill sponsors, the California Academy of Physician Assistants, for several years on legislative proposals that have increased patient access to care. We support this bill because it provides a much-needed update to the law on the licensure and supervision of physician assistants. The recently proposed amendments clarify and focus the scope of the bill so that it is more understandable. This legislative proposal will enable our Medical Groups to further augment our services to patients."

"PAs increase the reach of a medical practice. They are well-received by patients for their skill and care. PAs are the plentiful, youthful, and vital component of the California healthcare workforce for today and the future."

The *California Medical Association* (CMA) writes, "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 removing fees for supervising physician assistants, 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. [This bill] also removes confusing chart review requirements, leaving in any necessary chart review to be determined by the supervising physicians. 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."

ARGUMENTS IN OPPOSITION:

The *California Chapter of the American College of Emergency Physicians* are opposed unless amended, writing, "under the current supervision system there is a clearly defined relationship between PAs and the physicians that supervise them. Under the structure proposed in [this bill], this relationship is lost, as there is no requirement to identify which physician is supervising which PA. In the [emergency department] setting this exposes every physician to potential liability for actions of a PA, rather than narrowing it to the physician supervising at the time of

the alleged incident. Similarly, PA's for other specialties often provide on-call services in the ED. In some cases, emergency physicians may want to consult directly with the supervising specialist physician rather than the PA, a practice protected by current statute that would be eliminated by [this bill].

The *Physician Assistant Board* is opposed unless amended, seeking:

1) The removal of the references to "organized health care system" because the board believes it allows for the corporate practice of medicine;

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;

4) The addition of language limiting the services a physician may delegate "to those tasks and procedures consistent with the supervising physician's specialty or usual and customary practice and with the patient's health condition;

5) And restoration of the current language regarding drug ordering and prescribing, rather than references to furnishing and ordering.

IMPLEMENTATION ISSUES:

Initialisms. Currently, the agreements between physician assistants and physicians are called delegation of services agreements, or DSAs, for short. As a result, the new term, practice agreement, might be initialized to PA in conversation or otherwise. However, the term physician assistant is often initialized (and defined under this bill) as PA. If this bill passes this committee, the author may wish to work with the sponsor and other stakeholders to determine a name for the new agreement that does not share the same initials as the practitioners.

AMENDMENTS:

1) *Supervision*. The bill specifies that "supervision" shall not be construed to require the physical presence of a physician and surgeon. While this is language taken from the nursing practice act, the PAB believes it could be construed to prevent the PAB and the Medical Board of California from disciplining a licensee when patient harm resulted from a practice agreement that did not require physical presence, as well as limit the boards' authority to require physical presence if a physician or PA is on a probationary or other conditional license. Therefore, the Committee may wish to amend the bill to clarify that physical presence can be required pursuant to a practice agreement and to disciplinary orders:

   On page 4, lines 34-35, strike "surgeon." and insert:

   (f) *(1)* "Supervision" means that a licensed physician and surgeon oversees the activities of, and accepts responsibility for, the medical services rendered by a

physician assistant. Supervision, as defined in this subdivision, shall not be construed to require the physical presence of the physician and ~~surgeon.~~ *surgeon, but does require the following:*
(A) Adherence to adequate supervision as agreed to in the practice agreement.

(B) The physician and surgeon be 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 or probation.

2) *Regulations*. The bill defines "regulations" throughout the PA Practice Act as the regulations read on June 7, 2019. According to the author and sponsors, this was a drafting error meant only to apply to the provisions relating to the pharmacology requirements. Therefore, the Committee may wish to amend the bill to delete the reference:

Page 4, lines 37-38, strike "Regulations, as those provisions read on June 7, 2019" and insert "Regulations.":

(g) "Regulations" means the rules and regulations as set forth in Division 13.8 (commencing with Section 1399.500) of Title 16 of the California Code of ~~Regulations, as those provisions read on June 7, 2019.~~ *Regulations.*

3) *Organized Health Care Systems*. This bill authorizes organized health care systems to collaborate with physicians and surgeons in developing practice agreements. Because organized health care systems are not necessarily medical or other professional corporations allowed to practice medicine, the Committee may wish to amend the bill to clarify that organized health care systems must comply with corporate practice requirements under the Medical Practice Act:

On page 5, line 10, strike "services." and insert: and is in compliance with Article 18 (commencing with Section 2400), of Chapter 5.":

(j) "Organized health care system" includes a licensed clinic as described in Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code, an outpatient setting as described in Chapter 1.3 (commencing with Section 1248) of Division 2 of the Health and Safety Code, a health facility as described in Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, a county medical facility as described in Chapter 2.5 (commencing with Section 1440) of Division 2 of the Health and Safety Code, an accountable care organization, a home health agency, a physician's office, a professional medical corporation, a medical partnership, a medical foundation, and any other entity that lawfully provides ~~medical services.~~ *services and is in compliance with Article 18 (commencing with Section 2400), of Chapter 5.*

REGISTERED SUPPORT:

California Academy of PAs (sponsor)

America's Physician Groups
Association of California Healthcare Districts, and Affiliated Entity Alpha Fund
California Academy of Family Physicians
California Association for Health Services At Home
California Hospital Association
California Medical Association
California Psychiatric Association
Californiahealth+ Advocates
Medical Board of California

REGISTERED OPPOSITION:

California Chapter of the American College of Emergency Physicians (unless amended)
California Rheumatology Alliance (unless amended)
California Society of Plastic Surgeons
Physician Assistant Board (unless amended)
1 individual (unless amended)

Analysis Prepared by: Vincent Chee / B. & P. / (916) 319-3301

Attachment 5

DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. PHYSICIAN ASSISTANT BOARD

PROPOSED REGULATORY LANGUAGE
SB 697 Implementation

Legend:	Added text is indicated with an underline. Omitted text is indicated by (* * * *) Deleted text is indicated by ~~strikeout~~.

Amend Section 1399.502 of Article 1 of Division 13.8 of Title 16 of the California Code of Regulations to read as follows:

§1399.502 Definitions.

For the purposes of the regulations contained in this chapter, the terms

(a) "Board" means Physician Assistant Board.

(b) "Code" means the Business and Professions Code.

~~(c) "Physician assistant" means a person who is licensed by the board as a physician assistant.~~

~~(d) "Trainee" means a person enrolled and actively participating in an approved program of instruction for physician assistants.~~

(c~~e~~) "Approved program" means a program for the education and training of physician assistants which has been approved by the ~~b~~Board.

~~(f) "Supervising physician" and "physician supervisor" mean a physician licensed by the Medical Board of California or a physician licensed by the Osteopathic Medical Board of California.~~

(d~~g~~) "Approved controlled substance education course" means an educational course approved by the ~~b~~Board pursuant to section 1399.610.

(e) "Practice agreement" means the definition set forth in Section 3501(k) of the Code and it must contain the elements described in Section 3502.3 of the Code.

(f) "Supervision" means the definition set forth in Section 3501(f) of the Code.

NOTE: Authority cited: Section 3510, Business and Professions Code. Reference: Section 3510, Business and Professions Code.

Amend Section 1399.540 of Article 4 of Division 13.8 of Title 16 of the California Code of Regulations

§1399.540. Limitation on Medical Services.

~~(a) A physician assistant may only provide those medical services which he or she is competent to perform and which are consistent with the physician assistant's education, training, and experience, and which are delegated in writing by a supervising physician who is responsible for the patients cared for by that physician assistant.~~

(~~b~~a) ~~The writing which delegates the medical services shall be known as a delegation of services agreement.~~ 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.~~ each supervising physician. A delegation of services agreement may be signed by more than one supervising physician only if the same medical services have been delegated by each supervising physician. A physician assistant may provide medical services pursuant to more than one delegation of services agreement.~~

(~~c~~b) The ~~b~~Board or~~ Medical Board of California or their~~ its representative may require proof or demonstration of competence from any physician assistant for any tasks, procedures, or management ~~he or she is~~they are performing.

(~~d~~c) ~~A physician assistant shall consult with a physician regarding any task, procedure, or diagnostic problem which the physician assistant determines exceeds his or her level of competence or shall refer such cases to a physician.~~ If any task, procedure, or diagnostic problem exceeds the physician assistant's level of competence, they shall either consult a supervising physician and surgeon, or refer the patient to a physician and surgeon or licensed healthcare provider competent to render the services needed for the task, procedure, or diagnosis.

NOTE: Authority cited: Sections 2018, 3502 and 3510, Business and Professions Code. Reference: Section 3502, 3502.3, 3509, 3516 and 3527, Business and Professions

Amend Section 1399.541 of Article 4 of Division 13.8 of Title 16 of the California Code of Regulations

§1399.541. Medical Services Performable.

~~Because physician assistant practice is directed by a supervising physician, and a physician assistant acts as an agent for that physician, the orders given and tasks performed by a physician assistant shall be considered the same as if they had been given and performed by the supervising physician. Unless otherwise specified in these regulations or in the delegation or protocols, these orders may be initiated without the prior patient specific order of the supervising physician.~~

In any setting, including for example, any licensed health facility, out-patient settings, patients' residences, residential facilityies, and hospices, as applicable, a physician assistant may, pursuant to a delegationpractice agreementand protocols where present:

(a) Take a patient history; perform a physical examination and make an assessment and diagnosis therefrom; initiate, review and revise treatment and therapy plans including plans for those services described in Section 1399.541(b) through Section 1399.541(ii) inclusive; and record and present pertinent data in a manner meaningful to the physician.

(b) Order or transmit an order for x-ray, other studies, therapeutic diets, physical therapy, occupational therapy, respiratory therapy, and nursing services.

(c) Order, transmit an order for, perform, or assist in the performance of laboratory procedures, screening procedures, and therapeutic procedures.

(d) Recognize and evaluate situations which call for immediate attention of a physician and institute, when necessary, treatment procedures essential for the life of the patient.

(e) Instruct and counsel patients regarding matters pertaining to their physical and mental health. Counseling may include topics such as medications, diets, social habits, family planning, normal growth and development, aging, and understanding of and long-term management of their diseases.

(f) Initiate arrangements for admissions, complete forms and charts pertinent to the patient's medical record, and provide services to patients requiring continuing care, including patients at home.

(g) Initiate and facilitate the referral of patients to the appropriate health facilities, agencies, and resources of the community.

(h) Administer or provide medication to a patient, or issue or transmit drug orders orally or in writing in accordance with the provisions of subdivisions (a)-(f), inclusive, of Section 3502.1 of the Code.

(i)(1) Perform surgical procedures as authorized by the practice agreement and in accordance with the requirements of Section 3502 of the Code. Perform surgical procedures without the personal presence of the supervising physician which are customarily performed under local anesthesia. Prior to delegating any such surgical procedures, the supervising physician shall review documentation which indicates that the physician assistant is trained to perform the surgical procedures. All other surgical procedures requiring other forms of anesthesia may be performed by a physician assistant only in the personal presence of a supervising physician.

(2) A physician assistant may also act as first or second assistant in surgery under the supervision of a supervising physician as authorized by the practice agreement and in accordance with the requirements of Section 3502 of the Code. The physician assistant may so act without the personal presence of the supervising physician if the supervising physician is immediately available to the physician assistant. "Immediately available" means the physician is physically accessible and able to

~~return to the patient, without any delay, upon the request of the physician assistant to address any situation requiring the supervising physician's services.~~

(j) Perform any other services authorized by the practice agreement for which the physician assistant is qualified in accordance with the requirements of Section 3502 of the Code.

NOTE: Authority cited: Sections 2018, 3502 and 3510, Business and Professions Code. Reference: Sections 2058, 3501, 3502, ~~and~~ 3502.1, 3502.3 and 3509, Business and Professions Code.

Amend Section 1399.545 of Article 4 of Division 13.8 of Title 16 of the California Code of Regulations

§1399.545. Supervision Required.

(a) A supervising physician shall be available to receive inquiries~~, in person,~~ by telephone, or by other electronic communication ~~at all times~~ when the physician assistant is ~~caring~~providing medical services for patients.

~~(b) A supervising physician shall delegate to a physician assistant only those tasks and procedures consistent with the supervising physician's specialty or usual and customary practice and with the patient's health and condition.~~

~~(c) A supervising physician shall observe or review evidence of the physician assistant's performance of all tasks and procedures to be delegated to the physician assistant until assured of competency.~~

~~(d) The physician assistant and the supervising physician shall establish in writing transport and back-up procedures for the immediate care of patients who are in need of emergency care beyond the physician assistant's scope of practice for such times when a supervising physician is not on the premises.~~

~~(e) A physician assistant and his or her supervising physician shall establish in writing guidelines for the adequate supervision of the physician assistant which shall include one or more of the following mechanisms:~~

~~(1) Examination of the patient by a supervising physician the same day as care is given by the physician assistant;~~

~~(2) Countersignature and dating of all medical records written by the physician assistant within thirty (30) days that the care was given by the physician assistant;~~

~~(3) The supervising physician may adopt protocols to govern the performance of a physician assistant for some or all tasks. The minimum content for a protocol governing diagnosis and management as referred to in this section shall include the presence or absence of symptoms, signs, and other data necessary to establish a diagnosis or assessment, any appropriate tests or studies to order, drugs to recommend to the patient, and education to be given the patient. For protocols governing procedures, the protocol shall state the information to be given the patient, the nature of the consent to~~

~~be obtained from the patient, the preparation and technique of the procedure, and the follow-up care. Protocols shall be developed by the physician, adopted from, or referenced to, texts or other sources. Protocols shall be signed and dated by the supervising physician and the physician assistant. The supervising physician shall review, countersign, and date a minimum of 5% sample of medical records of patients treated by the physician assistant functioning under these protocols within thirty (30) days. The physician shall select for review those cases which by diagnosis, problem, treatment or procedure represent, in his or her judgment, the most significant risk to the patient;~~

~~(4) Other mechanisms approved in advance by the board.~~

(~~f~~b) The supervising physician has continuing responsibility to follow the progress of the patient and to make sure that the physician assistant does not function ~~autonomously~~ without supervision. The supervising physician shall be responsible for all medical services provided by a physician assistant under ~~his or her~~their supervision.

NOTE: Authority cited: Sections 2018, 3502, 3502.3 and 3510, Business and Professions Code. Reference: Sections 3501, 3502, 3502.3 and 3516, Business and Professions Code.