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MEMORANDUM

DATE	January 29, 2024
TO	Physician Assistant Board (Board)
FROM	Kristy Schieldge, Regulations Counsel, Attorney IV Jasmine Dhillon, Legislative and Regulatory Specialist
SUBJECT	**12. Update, Discussion, and Possible Action on Proposal to Amend 16 CCR Sections 1399.502, 1399.540, 1399.541, and 1399.545 – SB 697 Implementation, Proposed Second Modified Text, and Consideration of Public Comments**

Background

Senate Bill (SB) 697 (Caballero, Chapter 707, Statutes of 2019) made numerous changes to Physician Assistant (PA) practice. 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 regulations needing changing were eventually split into two regulatory packages. The proposed amendments to title 16, CCR sections 1399.502, 1399.540, 1399.541, and 1399.545 were consolidated into a SB 697 Implementation rulemaking that implements the shift from the "delegation of services" model to a "practice agreement" model. When the Board began working on these regulations, rulemakings impacting physician practice required Medical Board of California's (MBC's) approval, which in May of 2021, the MBC granted for the SB 697 Implementation Proposed Text.

In July of 2021 the California Academy of Physicians (CAPA) sent the Board a letter raising concerns about language in the SB 697 Implementation Proposed Text. Then-Board President Juan Armenta, Board Vice President and PA Sonya Early, Executive Officer Rozana Khan, Analyst Jasmine Dhillon and Staff Services Manager Kirsty Voong, Board Counsel Michael Kanotz, and Regulations Counsel Karen Halbo met several times to discuss the concerns raised in CAPA's letter. On October 13, 2021, those individuals met with representatives from CAPA. Subsequently, additional meetings by those individuals named above without CAPA representatives in attendance and the Board was provided with revised proposed regulatory language (Text) for the SB 697 Implementation rulemaking. The Board approved and adopted the revised Text at the November 8, 2021, Board meeting. The passage of SB 806 (Roth, Chapter 649, Statutes of 2021) removed the Board from under MBC jurisdiction, so the revised SB 697 Implementation Text did not require MBC approval of the 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). The comment period ended on September 12, 2023, and the Board received three public comments. At the November 6, 2023 Board meeting, the Board approved Modified Text (Attachment 2) and adopted the revised regulatory language in response to the comments received. A 15-day public comment period on the

Modified Text began on December 5, 2023 and ended on December 20, 2023, and the Board received three public comments.

Summaries of and Proposed Responses to Public Comments on the Modified Text

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.

Comments from the California Academy of PAs (CAPA) - letter dated 12.12.23

Proposed amendments to 16 CCR section 1399.541
Comment No. 1: CAPA argues that the proposed regulation section for CCR section 1399.541 as noticed in the Modified Text does not accurately reflect the changes proposed from the Originally Proposed Regulatory Language noticed on July 28th. They note that the words "or sedation other than local anesthesia" are new to the December 5th language, yet they are not double underlined to accurately show the public what is proposed to be added by the Board.

Proposed Response: The Board accepts this comment and corrects the text as noted in the comment letter.

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

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

Comment No. 3: CAPA objects to the proposed requirements in subsection (i) of CCR section 1399.541 that would require a physician assistant to "ensure" that a supervising physician and surgeon both "reviews the evidence which indicates that the physician assistant is trained and qualified to perform the surgical procedures under such sedation" and "has performed an assessment of whether the patient's physical status and fitness is appropriate to undergo the procedure." CAPA argues the Board's proposal flips the legally established relationship between PA's and supervising physicians and surgeons upside down by attempting to establish a PA supervisorial relationship over a supervising physician and surgeon. The commenter asserts that current law establishes a physician and surgeon supervisory relationship with PAs through practice agreements contradicting this proposal (see specifically, Business and Professions Code (BPC) section 3501(f)). A regulatory proposal by the Board that mandates that a PA "ensure" that a physician and

surgeon do anything, including reviewing the training qualifications of PAs and conducting patient assessments, is unlawful and there is no statutory authority that will lawfully enable a PA to instruct physicians and surgeons to do anything. This is illustrated in BPC section 3502.3(a)(1)(c) which states the methods for the continuing evaluation of the competency and qualifications of the physician assistant, which is determined in the practice agreement between the physician assistant and supervising physician and surgeon.

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

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

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

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

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

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

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

Proposed Response to Comment No. 4: As noted in the response above, the Board has decided to strike this language as it interprets BPC sections 3502 as already

prescribing the minimum standards for medical services a physician assistant can perform.

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

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

In response to CAPA's foregoing comments the Board would amend the proposed text at CCR section 1399.541 as follows:

- Revising all existing and previously proposed text in subsection (i)(1) as follows:

  (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.*

- Revising all existing and previously proposed text in subsection (i)(2) as follows:

  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.~~

- Strike previously proposed text at subsection (i)(3), as follows:

> ~~*(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.*~~

Comment from the California Medical Association (CMA) – letter dated 12.20.23

Proposed amendments to 16 CCR section 1399.541
Comment No.1: The CMA comment proposes to amend 16 CCR section 1399.541(i)(1) to continue to place review of a physician assistant's qualifications on the supervising physician and surgeon, and to prevent a physician assistant from performing any procedures until that has happened. CMA is also requesting the Board change the word "evidence" to "documentation" as it is more difficult to determine what qualifies as "evidence".

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

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

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

Comment No. 3: Further, the CMA comments suggests the addition of the paragraph "Nothing in this section shall prohibit one or more supervising physicians and surgeons or a supervising physician and surgeon who is authorized to approve the practice agreement on behalf of the physicians and surgeons on the staff of an organized health care system in accordance with Section 3502.3(a)(2)(B) of the Business and Professions Code from

requiring the personal presence of a physician and surgeon when a physician assistant is performing any medical service, including surgical procedures, authorized through the practice agreement." CMA states that this paragraph would clarify that although the law cannot compel personal presence, the supervising physician and surgeon retains this discretion and may choose to require personal presence in a practice agreement with a physician assistant.

Proposed Response to Comment No. 3: The Board acknowledges this comment but does not agree to this addition as BPC section 3502.3(a)(1)(B) states that policies and procedures to ensure adequate supervision of the physician assistant are determined in the practice agreement, which is agreed upon by the physician assistant and supervising physician and surgeon and adding a personal presence requirement of any kind through regulation would conflict with BPC section 3501(f)(1) (supervision "shall not be construed to require the physical presence of the physician and surgeon."). This does not prevent the parties to any practice agreement from agreeing to require the personal presence of a physician and surgeon, and it is agreed upon between the supervising physician and surgeon and physician assistant as illustrated in the practice agreement. In accordance with this determination, the Board will be amending its proposal to strike any current or proposed references to "in-person" or "personal presence" requirements.

Comment from the California Orthopaedic Association (COA) – letter dated 12.20.23

Proposed amendments to 16 CCR section 1399.541
Summary of Comment: The COA comment recommended removing the term "the supervising" from CCR section 1399.541(i)(1) because any physician and surgeon can clear a patient for surgery, not just the supervising physician and surgeon. The Board has amended the text in CCR section 1399.541(i)(1) which includes removing "the supervising". Further, COA in agreement with CMA requests that adding the paragraph "Nothing in this section shall prohibit one or more supervising physicians and surgeons or a supervising physician and surgeon who is authorized to approve the practice agreement on behalf of the physicians and surgeons on the staff of an organized health care system in accordance with Section 3502.3(a)(2)(B) of the Business and Professions Code from requiring the personal presence of a physician and surgeon when a physician assistant is performing any medical service, including surgical procedures, authorized through the practice agreement" would add clarification to CCR section 1399.541.

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

Additional Concerns and Recommended Changes to the Proposed Text

Board President Sonya Earley, Board Vice President Vasco Deon Kidd, newly assigned Regulations Counsel Kristy Schieldge, and Specialist Jasmine Dhillon met to discuss possible additional changes to the proposed text. Upon their review, the following changes are being recommended.

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

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

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

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

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

(d) Striking references to personal presence requirements and limitations on surgical and anesthetic medicine in CCR section 1399.541(i) as noted above in response to CAPA's comments;

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

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

(f) Striking the word "competent" in CCR section 1399.541, subsection (j) (re-lettered from (k)) and add "qualified" and language consistent with the requirements in BPC section 3502 that must be met to perform services authorized by the practice agreement, to read:

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

(g) Striking the reference to "in person" requirements for supervision in CCR section 1399.545.

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

Action Requested

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

Option A: If the Board agrees with the proposed responses to comments and the proposed Second Modified Text, please entertain a motion to:

Adopt the proposed responses to comments and the Second Modified Text and direct staff to send the Second Modified Text in **Attachment 1** out for a 15-day public comment period. If no adverse public comments are received on the Second Modified Text, instruct the Executive Officer to take all steps necessary to complete the rulemaking process, authorize the Executive Officer to make any technical or non-substantive changes to the rulemaking package and adopt the amendments to 16 CCR sections 1399.502, 1399.540, 1399.541, and 1399.545, as noticed in the Second Modified Text.

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

Adopt the proposed responses to comments and direct staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes amendments to the Second Modified Text in **Attachment 1** discussed at this meeting [describe changes to Attachment 1 here]. If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt 16 CCR sections 1399.502, 1399.540, 1399.541, and 1399.545, as noticed in the revised Second Modified Text.

Attachment:
1. Proposed Second Modified Text
2. Previously Proposed Modified Text
3. California Academy of PAs (CAPA) 12.12.23 comment letter
4. California Medical Association (CMA) 12.20.23 comment letter
5. California Orthopaedic Association (COA) 12.20.23 comment letter
6. Letter from CAPA, dated November 12, 2020

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 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 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 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 ~~competent~~ 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.~~

~~(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

DEPARTMENT OF CONSUMER AFFAIRS

Title 16. PHYSICIAN ASSISTANT BOARD

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.

Omitted text is indicated by "* * * *"

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

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) ~~The writing which delegates the medical services shall be known as a delegation of services agreement.~~ A ~~delegation of services~~practice agreement shall be signed and dated by the physician assistant and one or more 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) 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) ~~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~~their ~~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 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 setting~~s~~, patients' residence~~s~~, 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) 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) Performance of surgical procedures without the personal presence of the supervising physician. ~~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. 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) Perform any other services authorized by the practice agreement for which the physician assistant is competent.

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~~b) 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.~~

(~~f~~c) 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 3

December 12, 2023

The Honorable Juan Armenta
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
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RE: CAPA Comment on Proposed Regulatory Language to Implement SB 697

Dear President Armenta 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) respectfully offers its comments to the proposed changes released December 5th. CAPA's comments are limited to one section of the Physician Assistant Board (PAB)'s proposed regulations for the implementation of SB 697; namely, proposed section 1399.541.

As detailed herein, some of the proposed changes to section 1399.541 of the proposed regulations would regrettably render the regulation facially unlawful because, in several ways, the proposal bluntly contradicts the plain language of binding law and would manifestly frustrate the legislative intent of SB 697.

Moreover, some of the proposed changes would be injurious to patients and impede patient-protecting enforcement. This is because some of the proposed changes are (i) flatly inconsistent with widespread and documented medical practice, (ii) would require senselessly redundant work by busy medical professionals diverting them from patient care, and would (iii) sow

foundational confusion in every setting in the State where surgical procedures are performed by PAs, including emergency settings, to the severe detriment of rational medical decision-making and hence patient care.

For the many reasons below, CAPA respectfully urges upon the PAB to revert to the prior proposed language for section 1399.541 from July 28th, reconsider the language CAPA previously communicated to the PAB on November 13th, 2020, or strike the proposed section of 1399.541(i) altogether.

THE PROPOSED SURGICAL PROCEDURES REGULATION.

The proposed regulation section 1399.541 excerpted below is copied from the PAB's website public notice, dated December 5th. The inconsistent highlighting is in the original posted on the PAB's website. We here quote only from the parts of the regulation for which changes are proposed in the December 5th text.

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

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 agreement:

(i)(1) Performance of surgical procedures without the personal presence of the supervising physician. 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 performingdelegating 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 evidencedocumentation which indicates that the physician assistant is trained and qualified to perform the surgical procedures under such sedation. The physician a s sistant 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 sSurgical procedures requiring other forms of procedural sedation or sedation other than local anesthesia, including general anesthesia may be performed by a physician assistant only whenin the personal presence of a supervising physician is immediately available during the procedure.[1]

With emphases supplied, the following excerpt from the PAB's January 2021 meeting appear to reflect the PAB's priorities for this regulation:

[1] https://pab.ca.gov/lawsregs/sb697_modtxt.pdf

MEMORANDUM

DATE	January 28, 2021
TO	Physician Assistant Board (Board)
FROM	Rozana Khan, Executive Officer Karen Halbo, Regulations Counsel, Attorney III

CAPA raised significant concerns about 16 CCR 1399.541 subdivision (i) paragraph (1) - regarding requiring supervision during surgical procedures; and subdivision (j) - regarding the language provided related to obtaining informed consent. CAPA cited to BPC section 3501, subdivision (f), paragraph (1), sub-paragraphs (A) & (B), saying that the Board lacks the authority to specify supervision requirements on a PA performing surgical procedures, and quoted BPC section 3501, subdivision (f), paragraph (1), which says that PA supervision cannot require the physical presence of the supervising physician.

Board president Armenta and former board president Grant and staff believe the Board can only meet its consumer protection mandate by requiring the supervising physician be "immediately available" when a PA is performing surgical procedures on a patient under general anesthesia. The phrase "immediately available" is already defined in detail in the existing language of 16 CCR 1399.541, subdivision (i), paragraph (2). Requiring the supervising physician to remain immediately available makes it possible for the supervising physician to return and take over or advise and assist the PA if something goes wrong. **This requirement simply defines what is "adequate supervision" under those circumstances. The supervising physician does not need to remain at the PA's side, or even in the operating room where the surgical procedures are taking place. The supervising physician is only required to remain nearby, where he or she can be reached and can return to the operating room should something go wrong.**

The Board has investigated a complaint where the PA was performing surgery on a patient under general anesthesia and something went wrong. Because the supervising physician was not immediately available to return and assist, the patient died. Allowing a PA to perform surgical procedures on a patient under general anesthesia without requiring the supervising physician to be immediately available during the procedures would create an untenable risk to the lives and health of California consumers. The proposed language does not, as CAPA asserts, require the physical presence of the supervising physician. The proposed language merely defines what is adequate supervision when a PA is performing surgical procedures on a patient under general anesthesia. This makes clear the level of supervision that must be agreed to in the practice agreement between a PA and a supervising physician who has a PA perform surgical procedures on patients under general anesthesia.

MODIFIED DECEMBER 5TH TEXT DOES NOT ACCURATELY REFLECT CHANGES TO THE JULY 28TH TEXT.

The PAB's website discloses to the public the proposed text from July, 28, 2023, that purports to precede the December 5th text, excerpted above.[2] Observe that the December 5th language does not accurately reflect the changes proposed from the July 28th language:

[2] https://pab.ca.gov/lawsregs/sb697language.pdf https://pab.ca.gov/lawsregs/sb697notice.pdf

Here is language from the July 28th text. Observe the words "local anesthesia, procedural sedation, or general anesthesia" in the first sentence, single underlined.

> Prior to a physician assistant performing~~delegating any such~~ surgical procedures under local anesthesia, procedural sedation, or general anesthesia, …

Here is the parallel text from the December 5th language, again with the original highlighting retained:

> 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 words "or sedation other than local anesthesia" are new to the December 5th language. Yet they are not double underlined, concealing from the public that these words are, in fact, newly proposed to be added by the PAB.

DISCUSSION OF CHANGES NEWLY PROPOSED FOR REGULATIONS SUBDIVISION (i)(1)

I. A Grammatical Error Should Be Fixed.

The proposed regulations depart from the language of the rest of the section that lists verb-by-verb tasks PAs may lawfully perform pursuant to a practice agreement (Examples: "Take," "Order," "Recognize," "Instruct," etc.) and substitutes "Performance" for "Perform." This substitution renders the operative sentence a grammatically incorrect sentence fragment and, at best confusing:

> In any setting … a physician assistant may, pursuant to a ~~delegation~~practice agreement:
>
> (i)(1) Performance of surgical procedures without the personal presence of the supervising physician.

CAPA PROPOSAL: CAPA respectfully suggests that the PAB delete "Performance" and restore "Perform".

II. The Proposed Regulation Unlawfully Elevates PAs to A Supervisorial Role Over Physicians and Surgeons.

For the first time the regulation is proposing in two instances to flip 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[3]-- a physician and surgeon (i) "reviews evidence" of the PA's procedural-related training and qualifications prior to

[3] https://www.merriam-webster.com/dictionary/ensure

a PA performing a surgical procedure and (ii) conducts their own assessment of the patient prior to a PA performing a surgical procedure. The relevant parts of the proposed regulation read:

> 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.

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 – the only way a PA can "ensure" they do anything -- the plain text of current law establishes a physician and surgeon supervisorial relationship with PAs through practice agreements, contradicting this proposal.

For example, proposed regulation subdivision (f) defines supervision: (f) "Supervision" means the definition set forth in Section 3501(f) of the Code. That Code section reads:

> (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. (Emphasis added)

The proposed upside down mandate on a PA to "oversee" the work of physicians and surgeons through "ensuring" they do things bluntly contradicts this statute.

III. The Proposed Regulation Unlawfully Elevating PAs to A Supervisorial Role Over Physicians and Surgeons When It Comes To a Physician Reviewing PA Qualifications and a PA Ensuring Physicians Assess Their Patients Frustrate Patient Care.

Aside from being unlawful, the proposed regulations requiring PAs to "ensure" that physicians do their jobs both simply makes no sense and dangerously distracts busy medical professionals away from patient care to complete senseless busy work. The practical absurdity of the proposal is revealed when one imagines it being applied to other licensed professions or workplaces:

- Would the State Bar seriously consider promulgating a rule enforced by Bar discipline that required a law firm partner, prior to assigning a task to an associate, each time to review the CV and employee file of the colleague prior to doing so?

- More analogously, would the State Bar require an associate to "ensure" that the senior partner supervising them had performed this qualification review?

- Would the PAB's Executive Officer, prior to beginning to work on an assignment from the PAB, inquire of each of the Members whether they have each re-examined her resume and employee file?

- Would a staff member of the PAB, prior to accepting an assignment from the E.O., inquire each and every time whether the E.O. had first reviewed their CV and employee file to "ensure" the E.O. had done so? Could the staff member proceed with the task assigned them before "ensuring" their supervisor had done so?

Beyond these comparisons, discussing how these proposals would actually play out in a medical clinical setting reveals why they pointlessly frustrate patient care and why, respectfully, they cannot become law. Consider the following as applied to a PA "ensuring" a physician and surgeon reviews the PA's qualifications and training. Suppose a PA had been authorized to reduce a dislocated shoulder on a Monday. Under the proposal, if the PA was authorized to perform exactly the same procedure on a Tuesday, the PA would have to, before-hand, somehow "guarantee" that a physician and surgeon redundantly reviewed the PA's qualifications to do the very thing they did the day before. And, so on. Day after day after day after redundant day.

The same impractical absurdity exists with the proposal that PA's "ensure" physicians and surgeons have "assessed" their patients. Consider a hospital where, on a Wednesday, several patients are seen by the PA who need a simple chest tube inserted. Under this regulatory proposal, a PA would no longer, pursuant to a practice agreement entered onto with physicians and surgeons, be permitted to perform these routine procedures throughout the day, despite the PA being legally permitted to do so pursuant to Business & Professions Code section 3502 and ***despite already being authorized to do so by a physician and a practice agreement*.** Rather, under the proposed regulation, upon seeing the patient, the PA prior to inserting the chest tube, and subjecting the patient to a delay in care, would have to go back to the supervising physician and surgeon and ask "have you assessed this patient?" And, later, throughout the day and every day, each time: "What about this patient? And this one? And this one?"

In sum, no matter how many times a PA had performed a surgical procedure, no matter the terms of the practice agreement, no matter the trust earned between two collaborating medical professionals, and even if the PA had more experience than the physician and surgeon, under these proposals the PA each and every time would have to somehow "guarantee" ***their supervisor*** pulled up their resumes and employee files to review their qualifications to do that which they may have done hundreds of times, with, by definition, a physician's oversight.

But that's not all. With no apparent appreciation for the busy clinical schedules of both PAs and the physicians and surgeons, the proposal also requires the PA somehow to interrupt the physician and surgeon during their day to "ensure" the physician and surgeon – again, the PA's legal supervisor -- performed an assessment that the physician and surgeon may already have

done or may have lawfully authorized a PA to do. Respectfully, these proposals make no sense. Both of them pointlessly delay and frustrate patient care.[4]

IV. The Proposed Regulation Unlawfully Elevating PAs to A Supervisorial Role Over Physicians and Surgeons When It Comes To a Physician Assessments Unlawfully Overrides And Contradicts PA Practice and the Laws Establishing the Primacy of Practice Agreements.

PAs are lawfully entitled to perform surgical procedure patient assessments if the requirements of Business & Professions Code sections 3502 and 3502.3 are met – period. Because the proposed regulation strips from a physician and surgeon the ability to authorize a PA to perform surgical procedure assessments without the physician and surgeon repetitively and redundantly having to them, too, the proposed change unlawfully removes from PAs and physicians and surgeons the statute-protected ability to shape and nuance their supervisorial relationships in practice agreements. For this reason, too, the regulation is as newly proposed unlawful.

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.

Next, the statute also provides a PA "may perform medical services" -- i.e., a ***PA has a statute-based right to practice*** -- "if the following conditions are met". This means that so long as the "conditions" listed in section 3502 are met, ***the PA has a legal right to practice according to and under the provisions of the practice agreement and no regulation may lawfully impose additional requirements as a precondition to PA practice of any procedure beyond those listed in section 3502***. This is what is meant when President Grant correctly observes as he has that "PAs … practice is … authorized." Indeed, when President Grant suggests altering a regulation because it is "the writing [i.e., practice agreement] which authorizes the medical services to be performed," he is correct, and the extant regulation is unlawful for this very reason. This is what SB 697 was, in fact, all about:

[4] CAPA is respectfully confused about the origin of the proposal. It, respectfully, appears to come out of nowhere. As the excerpt from the PAB's memo above reveals, and as underscored by the PAB's and CAPA's conversations on this topic and section, the dominant concern expressed by PAB members about PAs and surgery orbited around the availability of a physician to return to aid patients in surgery under general anesthesia. This is reflected in the Memorandum excerpt in the text. CAPA respectfully cannot recall concerns about the qualifications of PAs that were so profound as to, as here, warrant an unlawful departure from the statute-mandated model of "authorization" for PA's through practice agreements.

> [T]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.

Assembly Business & Professions Committee analysis and explanation of SB 697, July 9, 2019, p. 5 (emphasis supplied).[5]

Thus, except for those enumerated restrictions on PA practice set forth in Business & Professions Code 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 who does assessments when -- are by decree of state law exclusively a matter between the parties to a practice agreement***. If the requirements of this statute are met, ***a PA may lawfully do the things authorized by the practice agreement and no regulation that impedes, conditions, or sequences that entitlement is a lawful one. Whether a PA may perform a surgical procedure after the PA's own "assessment" is no exception. The PAB is likewise not empowered to prevent or in any way, shape, or form condition a physician and surgeon from authorizing a PA to perform assessments.***

Business & Professions Code section 3502.3 likewise clarifies that anything lawfully within the scope of a PA is something a practice agreement can authorize. With emphasis supplied, that statute provides:

> (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**.

Respectfully, it is under state law the practice agreement between medical professionals practicing in a variety of clinical settings and not generally applicable PAB regulation that determines whether and how PAs may perform surgical procedure "assessments."(*See*, subparagraph (A).) Respectfully, it is the practice agreement between medical professionals practicing in a variety of clinical settings not generally applicable PAB regulation that determines the "methods" of "evaluation of the competency and qualifications of the" PA. (*See*,

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

subparagraph(C).) Deviations from the standards of care for these professionals are disciplinary matters not matters for generally applicable rule-making governing the entire populations of both professions.

In sum, and not even discussing that "assessment" has no solid medical meaning so the PA would never know whether they were in compliance with the proposed regulation, this newly proposed "assessment" requirement unlawfully (i) invades ***a physician's*** statutory right to practice by preventing ***a physician*** from authorizing to a PA surgical procedure assessments, (ii) invades ***a PA's*** statutory right to practice under Business & Professions Code sections 3502 and 3502.3 by categorically preventing ***the PA*** from doing such assessments when authorized by a physician and surgeon and practice agreement to do so, and (iii) interferes with the SB 697, statute-based right of these two medical professionals with plenary scopes of practice accountable for their behavior to their respective licensing boards definitively to shape their relationship and collaboration through practice agreements.

V. The Proposed Regulation Unlawfully Elevating PAs to A Supervisorial Role Over Physicians and Surgeons When It Comes To a Physician Assessments Contradicts Other Sections of the Regulations.

Furthermore, the new proposal regarding assessments contradicts proposed regulation section 1399.541 which reads:

> 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.

Again, according to this new proposal, an assessment performed by the PA is not "the same" as one performed by a supervising physician. In fact, the new proposal further contradicts its own established regulations in section 1399.541(a) which reads (emphasis supplied):

> (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) inclusive**; and record and present pertinent data in a manner meaningful to the physician.

The proposal seeks to remove a PA from doing, or even relying, on their own "assessments."

VI. The Proposed Regulation Unlawfully Elevating PAs to A Supervisorial Role Over Physicians and Surgeons When It Comes To a Physician Assessments Unlawfully Violates SB 233 and, in Doing So, Gravely Imperils Patient Safety.

Lastly, by stripping PAs of their ability to perform surgical procedure assessments when they are legally authorized to do so, the new proposed regulation also:

1. Unlawfully contradicts SB 233 (Pavley, 2011) which amended Health and Safety Code section 1317.1 to allow PAs to be recognized in providing emergency services and care.

2. Unlawfully contradicts the federal Emergency Medical Treatment and Active Labor Act which "allows an on-call physician, under hospital policies, the option of sending a representative, i.e., directing a non-physician practitioner or his/her representative to appear at the hospital and provide further **assessment** or stabilizing **treatment** to an individual."[6] (Emphasis on "assessment" and "treatment" added.)

3. Deviates, with possibly lethal consequences, from clinical emergency practice as there "are some instances in which the non-physician practitioner can provide the specialty treatment more expeditiously than the physician on-call."[7]

Here, the new proposal would restrict the ability of the PA to provide certain emergency assessments and therefore emergency procedures even when the PA is lawfully permitted to provide such emergency assessments and therefore emergency procedures under Business & Professions Code section 3502 (*i.e.*, the PA is authorized to do so by a practice agreement and their education, training and experience prepares them to do so) until the PA:

- leaves the emergency patient's bedside,
- sprints to find their supervising physician and surgeon,
- interrupts them in whatever they are doing (they may themselves be in the midst of an emergency) to obtain a note, a nod, a verbal guarantee that the physician and surgeon has "assessed" the patient the PA is treating when that (i) may not be possible and (ii) that assessment may the PA's job under a practice agreement.

Then the PA will also have to:

- ensure the supervising physician and surgeon has reviewed a print out of the PA's training records and employee file to validate the PA's qualifications to save the waiting patient's life.

Only after all these things are done can the PA return to the task of treating the emergency room patient. This is exactly what the Legislature blocked in enacting SB 233.

Regulations by definition must at some level be one-size-fit all. In dramatic contrast, collaborations of medical professionals that are implemented in real-time against ever-changing patient care needs and delivery exigencies, cannot safely be and are not wisely one-size-fit all. That's exactly the reason why SB 697 takes the approach it does and that is exactly why this approach is in the Legislature's view in the best interests of patients. Again, as former PAB

[6] Assembly Health Committee analysis, SB 233, July 5, 2011.
[7] Ibid. See also See CMS Interpretive Guidelines for Hospitals in Emergency Cases https://www.cms.gov/Regulations-and-Guidance/Guidance/transmittals/downloads/R46SOMA.pdf

President Grant has correctly observed, it is "the writing [i.e., practice agreement] which authorizes the medical services to be performed."

VII. The Proposed Change Creates An Internal Conflict Within The Proposed Regulations.

This new proposal requiring the PA to monitor the work of physicians and surgeons also contradicts proposed regulation section 1399.541 which reads:

> 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.

No, in fact, when it comes to surgical procedures, a PA may not "perform a task" that is "the same as if the action had been … performed by a supervising physician" under the new proposal because a PA must somehow compel a physician to "ensure" the PA is themself qualified and trained to do the thing the physician has already determined the PA is qualified and trained to do by dint of the task being assigned to the PA under a practice agreement.

VIII. The Proposed Regulation Misapprehends Anesthetic Medicine.

The prior regulation correctly and clearly enumerated three categories of pain management during surgical procedures: **"**local anesthesia, procedural sedation, or general anesthesia."

The proposed regulation incorrectly and for the first time appears to assert the existence of a hierarchical medical relationship between "sedations." The regulation initially asserts that "local anesthesia" is always a subcategory of "sedation": "… or sedation other than local anesthesia".

Next, the regulation incorrectly asserts that "general anesthesia is a form of "sedation," one that is different that the sedation of "local anesthesia": "… or sedation other than local anesthesia, including ~~procedural sedation, or~~ general anesthesia."

Medically speaking, neither of these are true. The newly proposed regulations here confusingly depart from standard medical practice and terminology. Since at least 2012, the PAB has been aware of the lack of regulatory clarity around this topic as regulations enacted prior to SB 697 incorrectly discussed surgical procedures performed under "local anesthesia" versus "other forms of anesthesia"; this prior error is now uploaded to the current draft and the error is this: ***procedural sedation is not a form of anesthesia***. The proposed language of "sedation other than local anesthesia," which "includes general anesthesia," subverts the prevailing consensus from both CMS and the American Society of Anesthesiologist as it relates to commonly understand definitions of local anesthesia, procedural sedation, and general anesthesia.[8]

[8] See CMS Interpretive Guidelines for Hospitals utilizing the American Society of Anesthesiologists definitions. https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/scletter11_10.pdf

That the proposed regulations get this medical issue wrong provides further evidence as to why SB 697 leaves practice to two medical professionals that have plenary scopes of practice.

As both the pre-SB 697 regulation and the new draft are simply not consistent with standard medical terminology, efforts by PAs and physicians and surgeons to obey these regulations will pointlessly push them away from medicine and science-based practice that benefits patients toward efforts to comply with a regulation which is not based on science or medicine, to the detriment of patients.

CAPA PROPOSAL

CAPA respectfully suggests deleting the language requiring a PA to "ensure" a supervising physician re-check the PA's qualifications and delete the language requiring a PA to "ensure" a supervising physician re-check a PA's assessment prior to a surgical procedure. CAPA respectfully suggests a return to the language noticed on July 28th, strike the language found in 1399.541(i) altogether, or reconsider the clear and concise language previously suggested from CAPA to the PAB for Section 1399.541 dated November 13th, 2020:

(i) (1) Perform surgical procedures as authorized by the practice agreement; which the PA is competent to perform and consistent with the PA's education, training, and experience, and rendered under the supervision of a licensed physician and surgeon in accordance with Section 3502 of the Business and Professions Code.

(i)(2) A physician assistant may also act as first or second assistant in surgery as authorized by the practice agreement; which the PA is competent to perform and consistent with the PA's education, training, and experience, and rendered under the supervision of a licensed physician and surgeon in
accordance with Section 3502 of the Business and Professions Code.

CONCLUSION

With gratitude for the opportunity to comment on 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, I remain

Very truly yours,

Scott Martin
President, California Academy of PAs

Attachment 4

CALIFORNIA MEDICAL ASSOCIATION

December 20, 2023

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

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

RE: Proposed Regulatory Language for SB 697 Implementation

Dear Ms. Dhillon,

On behalf of the California Medical Association (CMA) and our nearly 50,000 physician and medical student members, CMA writes to respectfully request further amendments to the proposed regulations implementing the statute adopted by SB 697.

First, CMA would like to take this opportunity to thank the Physician Assistant Board ("Board") staff again for their thorough analysis of the letter CMA submitted in response to the draft regulations noticed on July 28 and the amendments proposed by the Board.

CMA offers additional recommendations to the Board to advance our common goals of ensuring patient safety and consumer protection. Our comments seek to clarify the Board's proposed requirements for a physician assistant to perform surgical procedures on patients without the personal presence of the supervising physician and surgeon to reduce confusion during implementation.

I. CMA Proposed Amendments to Board Proposal in Section 1399.541(i)(1)

CMA requests amendments to Section 1399.541(i)(1) relating to a physician assistant's ability to perform surgical procedures on patients, particularly under sedation, including general anesthesia, without the personal presence of the supervising physician. CMA believes our proposed amendments make clear what requirements are being placed on the physician assistant and appropriately protect patients undergoing surgical procedures.

CMA's proposed amendments to Section 1399.541(i)(1) follow below. The language shows CMA's suggested changes to the Board's December 5, 2023, modified text as proposed to be amended:

> *Performance of surgical procedures without the personal presence of the supervising physician.* ~~***Prior to a***~~ ***A*** *physician assistant* ***shall not*** *perform*~~***ing***~~ *surgical procedures*

under local anesthesia or sedation other than local anesthesia, including general anesthesia, ***unless*** *the* ~~***physician assistant***~~ ***supervising physician*** ~~***shall ensure the supervising physician***~~ *reviews the* ***documentation*** ~~***evidence***~~ *which indicates that the physician assistant is trained and qualified to perform the surgical procedures under such sedation.* ***A*** ~~The~~ *physician assistant shall* ***not perform surgical procedures under sedation other than local anesthesia, including general anesthesia, unless*** ~~***ensure the supervising***~~ *a physician and surgeon has performed an assessment of whether the patient's physical status and fitness is appropriate to undergo the procedure. Surgical procedures requiring sedation other than local anesthesia, including general anesthesia may be performed by a physician assistant only when a supervising physician is immediately available during the procedure.*

The Board's December 5, 2023, modified text deleted the reference to procedural sedation and shifted some responsibility for the supervising physician and surgeon's review of the evidence of the physician assistant's qualification to perform surgical procedures under any such sedation without the personal presence of the supervising physician and surgeon to the physician assistant.

First, CMA would like to thank the Board for deleting the reference to procedural sedation in this December 5, 2023, modified text, as the term "procedural sedation" lacks a clear definition and is best removed from the regulations. However, the Board's December 5, 2023, proposed language requiring the physician assistant to ensure the supervising physician and surgeon review the evidence is circular. The Board is effectively requiring that the physician assistant ensure the supervising physician and surgeon has ensured the physician assistant is qualified to perform the procedure. CMA has rephrased this sentence to continue to place review of a physician assistant's qualifications on the supervising physician and surgeon, and to prevent a physician assistant from performing any such procedures until that has happened. CMA believes this maintains the intent of the originally proposed language while making each party's role in the process clearer.

CMA is also requesting the Board change the word "evidence" back to the former word "documentation." CMA believes "documentation" is clearer as it specifies what qualifies as evidence whereas the supervising physician and surgeon may have more difficulty determining what qualifies as "evidence" without that specificity. Additionally, documentation review is already the standard. Maintaining the current language will reduce confusion upon implementation of the revised regulations.

CMA's suggested amendments also make changes to the sentence regarding the physician assessment prior to undergoing surgery by a physician assistant without the personal presence of the supervising physician and surgeon.

At its November 6, 2023, meeting, the Board approved adding language which requires a physician assistant to ensure the supervising physician has performed an assessment of the patient's physical status and fitness for the procedure prior to the physician assistant performing the procedure. CMA recommends rephrasing this sentence in the same way as recommended for the previous sentence to eliminate circular responsibility.

Next, CMA suggests excluding surgical procedures performed using local anesthesia from this requirement. CMA appreciates the Board's commitment to patient safety in deciding to add a physician assessment of fitness for surgery prior to a physician assistant performing surgery without the personal presence of the supervising physician. However, for surgical procedures involving local anesthesia, CMA believes requiring such an assessment could disrupt current practice as the current regulations allow physician assistants to perform surgery under local anesthesia without the personal presence of the supervising physician and surgeon and do not currently require an assessment prior to such a procedure.

Finally, CMA also believes allowing any physician and surgeon to perform this assessment would create some flexibility in, for example, situations when the supervising physician and surgeon is not an anesthesiologist, but an anesthesiologist would be best fit to perform the required assessment.

II. Addition of Clarifying Language to Section 1399.541

CMA has received feedback from a number of its physician members across various specialties and modes of practice expressing concern with what they interpreted to be the creation of a uniform standard applicable in all instances allowing physician assistants to perform surgery without the personal presence of the supervising physician and surgeon on patients under general anesthesia. CMA recognizes that the Board's intent with the amendment to Section 1399.541(i)is actually to ensure a basic and uniform level of patient safety by requiring that supervising physicians be immediately available when a physician assistant is performing surgery on patients undergoing sedation other than local anesthesia, including general anesthesia. It is not the Board's intent to limit practice agreements to this requirement if the supervising physician believes additional requirements are needed.

To clarify this misconception and further this mutual goal, CMA asks that the Board include language reiterating the supervising physician and surgeon's ability to require their personal presence when the physician assistant is performing any medical service, including surgery, through the practice agreement. This would make the regulation explicitly clear that, though the Board does not believe it has the authority to limit a physician assistant's practice in this way, the supervising physician and surgeon retains this authority. CMA suggests this language be added as a new second paragraph in the preamble of section 1399.541. The preamble as proposed to be amended would read as follows:

> *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.

Nothing in this section shall prohibit one or more supervising physicians and surgeons or a supervising physician and surgeon who is authorized to approve the practice agreement on behalf of the physicians and surgeons on the staff of an organized health care system in accordance with Section 3502.3(a)(2)(B) of the Business and Professions Code from requiring the personal presence of a physician and surgeon when a physician assistant is performing any medical service, including surgical procedures, authorized through the practice agreement.

In any setting, including for example, any licensed health facility, out-patient setting, patients' residence, residential facility, and hospice, as applicable, a physician assistant may, pursuant to a practice agreement:

CMA urges the Board to adopt this new language to clarify that while the Board believes the law cannot compel personal presence, the supervising physician and surgeon retains this discretion and may choose to require personal presence in a practice agreement with a physician assistant.

Thank you for your consideration of our input and perspective. CMA looks forward to working with the Board and other stakeholders to further our common goals 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 levensen@cmadocs.org.

Sincerely,

Lucas Evensen
Associate Director, Strategic Engagement
California Medical Association

Attachment 5

CALIFORNIA COA ORTHOPAEDIC ASSOCIATION

Strong as individuals. More powerful together.

Date: December 20, 2023

To: Members, Physician Assistant Board of California
From: Kim Stone, Stone Advocacy for COA
Re: Proposed regulations re SB 697 Implementation

Via email: jasmine.dhillon@dca.ca.gov

Dear Chair Berman and Members,

On behalf of the California Orthopaedic Association, I write with two comments about the proposed SB 697 implementation regulations.

First, we recommend removing the words "the supervising" from the regulations (highlighted below) so that the most relevant and available physician can provide surgical clearance.

We believe it is important for a physician and surgeon to clear a patient for surgery. It does not necessarily have to be the "supervising physician." Based on the surgical procedure and the patient's other co-morbidities, it might be more appropriate for their PTP, the anesthesiologist, cardiologist, or another MD to perform the evaluation. Thus, the reason COA is asking for this amendment.

Proposed amendment:

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~~ a 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

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CALIFORNIA COA ORTHOPAEDIC ASSOCIATION

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a physician assistant only when ~~in the personal presence of~~ a supervising physician is immediately available during the procedure.

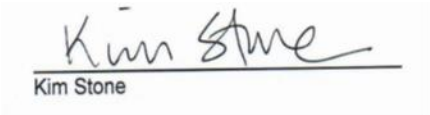
Second, we agree with the California Medical Association that adding the paragraph below would provide important clarification.

Nothing in this section shall prohibit one or more supervising physicians and surgeons or a supervising physician and surgeon who is authorized to approve the practice agreement on behalf of the physicians and surgeons on the staff of an organized health care system in accordance with Section 3502.3(a)(2)(B) of the Business and Professions Code from requiring the personal presence of a physician and surgeon when a physician assistant is performing any medical service, including surgical procedures, authorized through the practice agreement.

We urge the Board to include this language in the regulations.

Thank you for the opportunity to provide these comments.

Sincerely,



Kim Stone

Lobbyist, Stone Advocacy for COA

1246 P Street Sacramento, CA 95814 ♦ www.coa.org ♦ admin@coa.org
Phone: 916-454-9884 Fax: 916-454-9882

Attachment 6

November 12, 2020

The Honorable Denise Pines
President, Medical Board of California
Medical Board of California
Hon. Members of the Board
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815

The Honorable Jed Grant
President, Physician Assistant Board
Hon. Members of the Board
2005 Evergreen Street, Suite 1100
Sacramento, CA 95815

RE: REQUEST THAT THE PHYSICIAN ASSISTANT BOARD AMEND PENDING DRAFT REGULATIONS CONTRARY TO SB 697 (CABALLERO) AND TO OFFER AN OPPORTUNITY FOR MEANINGFUL PUBLIC INPUT OF AFFECTED LICENSEES PRIOR TO INCURRING THE EXPENSE OF FORMAL RULEMAKING

Dear Presidents Pines, Grant and Honorable Board Members:

On behalf of the over 13,000 physician assistants (PAs) licensed in California, the California Academy of PAs (CAPA) respectfully requests that the Physician Assistant Board (PAB) refrain from proceeding to formal rulemaking on certain draft regulations purporting to implement SB 697 (Caballero) but which, in fact, unlawfully frustrate and contradict that watershed legislation; legislation that should be implemented both without haste, meticulously, and collaboratively.

True, CAPA and the affected public can offer comment during an Administrative Procedures Act review process. However, given the sea change SB 697 represents for the PA profession, the self-executing nature of its key provisions, and the lack of urgency in implementing it through regulations, it also is a best practice to solicit and obtain public input before formally and irrevocably invoking this expensive process.

That has not happened and, respectfully, for the many reasons detailed below, it should.

Several Irregularities In The Public Disclosure Of The Draft SB 697 Regulations Frustrated Public Comment And, Therefore, Frustrated Proper Implementation Of The PAB's Own Resolution Not To Proceed To Formal Rulemaking If "Adverse Comments" Were Received.

It is not disputed that the PAB accidentally, but dramatically, departed from its standard practices in ways that made it harder for the public to be made aware that the PAB was in its August 7th meeting actually considering draft regulations as opposed to simply weighing whether to draft regulations. President Grant during the August 7th meeting properly spoke of his concern that the public had not seen the proposed regulations.

First, the agenda for the August 7th meeting does not say the PAB will consider actual draft regulations implementing SB 697 for PAB's consideration at that meeting. The August 7th agenda instead only announces the PAB's intent to discuss whether "to initiate" – to begin[1] -- a regulatory process which, of course, includes drafting. This, respectfully, is a far cry from an agenda item announcing consideration of regulations already drafted and poised to be approved for formal rulemaking. With emphasis added, the agenda item says:

> 14. Discussion and Possible Action **to Initiate a Rulemaking** to Amend Title 16, California Code of Regulations Sections 1399.502, 1399.506, 1399.507, 1399.511, 1399.530, 1399.540, 1399.541, 1399.545, and 1399.546 to include SB 697 Requirements (Halbo/Winslow)[2]

The Attorney General correctly explains that "agenda items should be drafted to provide interested lay persons with enough information to allow them to decide whether to attend the meeting or to participate in that particular agenda item."[3] That respectfully was not done here.

Second, and of course, if the PAB had adhered to its custom (and the practice of every other DCA board) of posting its upcoming board meeting materials on-line, the public would have seen that the PAB was, in fact, poised to weigh actual draft language as opposed to whether to "initiate" a regulatory path that includes such drafting. However, as President Grant's expressed concerns at the meeting illustrate, it is undisputed that posting did not occur *and has not occurred* at least as of November 10th.[4]

Thus, the first time the public was able through the Internet to see the actual proposed language was when the language was verbatim included not in an attachment labeled "draft regulations" but *in the minutes* of the August 7th meeting, distributed as a part of the PAB board packet for its November 9th meeting. In other words, it was not until the PAB posted its board packet for its November 9th meeting could the public without resorting to unusual measures realize that "initiate" as used on August 7th meant "review and approve draft regulations."

And, the draft regulations as reflected *in the minutes* offer an incomplete and therefore inadequate basis for substantive public comment. The materials in the August 7th meeting (again, counsel for CAPA received those on November 9th) provide detailed explanations of the PAB's view of SB 697, detail in some instances (but not all) reasons why staff believes the draft regulations are

[1] https://www.merriam-webster.com/dictionary/initiate
[2] https://www.pab.ca.gov/about_us/meetings/20200807_agenda.pdf
[3] https://oag.ca.gov/sites/all/files/agweb/pdfs/publications/bagleykeene2004_ada.pdf The minutes of the PAB meeting held immediately prior to the August 7th meeting likewise do not foreshadow imminent presentation of draft regulations.
[4] Counsel for CAPA only received those materials in an email upon his request on 11:52 am November 9th when the PAB meeting that day was nearly over.

warranted, and reveals the putative legal authorities for the draft regulations. Exactly none of that information, critical to being able to assess and comment upon the draft regulations, is present in the November materials.

Third, according to the minutes of the August 7th meeting, the PAB's adopted motion approving the draft regulations for formal rulemaking is *made expressly contingent upon their being no objection to them*. The adopted resolution states that PAB staff is only to proceed with formal rulemaking "if no adverse comments are receive [sic]."[5] The unintentional errors above made receiving such "adverse comments" all but practically impossible until now.

In sum, the PAB should not proceed now as it intended and unanimously resolved to do in August. Because (i) there is no urgency requiring proceeding immediately to formal rulemaking; (ii) that making changes through formal rulemaking is irrevocably and far more expensive than making changes informally now; and (iii) the over-arching importance of "getting it right" when it comes to implementation of SB 697's watershed changes, the PAB in August ***wisely and expressly resolved not to proceed to formal rulemaking if "adverse comments" were received. Given the admitted errors that occurred in disclosing to the public that draft regulations existed and were being formally weighed, it is, with respect, simply the best course to consider these comments as the "adverse" comments contemplated and for the PAB to grapple with them inexpensively and now in the manner it has already resolved to do; namely, before the commencement of formal rulemaking.***[6]

THE DRAFT SB 697 REGULATIONS ARE, IN SIGNIFICANT PART, BOTH UNLAWFUL AND UNWISE.

Reinforcing the PAB's wisdom of not proceeding to expensive formal rulemaking if adverse comments are received is the fact that the draft regulations are, in significant part, unlawful and, also, poor policy that would impede efficacious patient care.

We address each regulation where we have identified issues in turn.

REGULATION 1399.506. FILING OF APPLICATIONS

Subdivisions (e) and (f) PAB Proposed Changes:

> **1399.506. ~~Filing of~~ Applications for Licensure.**
>
> (e) As a condition of licensure, an applicant shall disclose whether they have any malpractice history and submit a written statement of any incident.
> (f) As a condition of licensure, an applicant shall disclose whether they have any disciplinary history from their school program or against any other licenses,

[5] https://www.pab.ca.gov/about_us/meetings/20201109_materials.pdf

[6] No motion was made at the November 9th meeting to overturn the resolution of the August 7th meeting to proceed only if "no adverse" comments were received. No formal motion was made or passed at the November 9th meeting to proceed with formal rulemaking. Thus, the PAB is still operating under the August 7th resolution wherein it was not supposed to proceed if "adverse comments" were received.

registrations, or certifications issued by any state and submit a written statement of any incident.

DISCUSSION: While CAPA might support legislation enabling something akin to this regulation, currently the PAB does not have a sufficiently clear legal basis to promulgate it, and it is unlikely it would survive OAL "authority" scrutiny. The authorities cited as vesting the PAB with the authority to require such self-disclosures are sections 2018, 3509, 3510, and 3513 of the Business and Professions Code.

Section[7] 2018 simply empowers the Medical Board to promulgate regulations and does not authorize the promulgation of self-disclosures by the PAB. Notably, and consistent with practice elsewhere, self-disclosure for physicians and surgeons is predicated on a specific statute; the kind entirely absent for PAs. *See*, for e.g., Business & Professions Code section 803.1(b) (physicians and surgeons) and Education Code section 94801.5(a)(1)(H) (out-of-state private postsecondary institutions).[8]

Moreover, section 3509 provides as follows:

> 3509. It shall be the duty of the board to:
>
> (a) Establish standards and issue licenses of approval for programs for the education and training of physician assistants.
> (b) Make recommendations to the Medical Board of California concerning the scope of practice for physician assistants.
> (c) Require the examination of applicants for licensure as a physician assistant who meet the requirements of this chapter.

The proposed regulation imposes a self-disclosure pre-condition for licensure. Outside of empowering the PAB to impose an examination for licensure, section 3509 does not address licensure in any fashion, and therefore, cannot serve as a lawful foundation for the licensing self-disclosure regulation.

Section 3510 simply permits the PAB to promulgate regulations when it has the lawful grounding for them and, importantly, requires the Medical Board's approval for some of the PAB's regulations. In any event, this statute does not offer the PAB carte blanche to promulgate any regulation it desires concerning pre-conditions for PA licensure.

The last section cited is 3513. It reads in full:

> The board shall recognize the approval of training programs for physician assistants approved by a national accrediting organization. Physician assistant training programs accredited by a national accrediting agency approved by the board shall be deemed approved by the board under this section. If no national accrediting

[7] All "section" references will be to the Business & Professions Code unless specified otherwise.
[8] As well, nurse practitioners are not subject to such a requirement. See, https://www.rn.ca.gov/pdfs/regulations/bp2834-r.pdf and https://www.rn.ca.gov/pdfs/applicants/npinstruct.pdf

> organization is approved by the board, the board may examine and pass upon the qualification of, and may issue certificates of approval for, programs for the education and training of physician assistants that meet board standards.

This statute has nothing to do with licensure let alone being a statute that enables the PAB to impose individual self-disclosure pre-conditions to licensure. It cannot and does not offer legal authority for the regulation.

SUMMARY: None of the statues cited by the PAB can lawfully serve as authority for the self-disclosure regulation and examples exist underscoring that specific legislation address self-disclosure – absent here – is required.

REGULATION 1399.540 LIMITATION ON MEDICAL SERVICES

Subdivision (a) PAB Proposed Changes:

> (a) A physician assistant may only provide those medical services which ~~he or she is~~ they are 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.

DISCUSSION: The regulation incompletely and, therefore, unlawfully implements section 3502 of SB 697 and creates an internal conflict within the regulation itself.

In subdivision (b) of the regulation, the PAB correctly proposes deleting a reference to services that are "delegated." As PAB President Grant trenchantly observed at the August 7th meeting, at p. 21 of the minutes:

> Mr. Grant commented that the way he understands the law is that the authorization for PAs to practice is no longer delegated, it is authorized. He would prefer that subdivision (b) read "the writing which authorizes the medical services to be performed shall be known as a practice agreement."

And as the PAB staff correctly explained in the August 7th board materials at p. 74 (emphasis added):

> 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.

Thus, to avoid internal inconsistencies the word "delegated" in (a) should be stricken as it is in (b). Moreover, the word "only" should be stricken because, as staff acknowledges, the practice agreement also serves as an additional possible basis for a PA providing services and no reference

to that agreement exists in the regulation. The regulation's use of the word "only" therefore creates an incomplete and, therefore, unlawful closed set of enumerated bases for PA practice.

CAPA RESPECTFULLY SUGGESTS:

Simply striking all of (a) and replacing it with the following:

> ~~(a) A physician assistant may only provide those medical services which he or she is they are 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.~~
>
> **(**a) A PA may provide those medical services which they are authorized to perform and which are consistent with the PA'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 of the Business and Professions Code.

Subdivision (b) PAB Proposed Changes:

> (b) The writing which delegates the medical services shall be known as a ~~delegation of services~~ practice agreement. A ~~delegation of services~~ practice agreement shall be signed and dated by the physician assistant and one or more 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~~. 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 agreement.~~

DISCUSSION: For the same reasons the word "delegation" is stricken in (b) the word "delegates" be stricken in the first sentence. Again, as President Grant correctly states, "the law is that the authorization for PAs to practice is no longer delegated, it is authorized."

CAPA RESPECTULLY SUGGESTS (additions in bold):

> (b) The writing which ~~**delegates**~~ **defines** the medical services **the PA is authorized to perform** shall be known as a ~~delegation of services~~ practice agreement. A ~~delegation of services~~ practice agreement shall be signed and dated by the ~~**physician assistant**~~ **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 physicians and surgeons on the staff of an organized health care system~~. 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 agreement.~~

1399.541. MEDICAL SERVICES PERFORMABLE[9]

PAB Proposed Changes:

> Because physician assistant practice is directed by a supervising physician, and a physician assistant acts as an agent for that physician and surgeon, 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~~ practice agreement 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 setting, patients' residence, residential facility, and hospice, as applicable, a physician assistant may, pursuant to a ~~delegation~~ practice agreement and where present, protocols:

DISCUSSION: This regulation, in several ways, no longer reflects the state of the law – is, in fact, in contradiction to it -- and, thus, is unlawful. Again, as President Grant correctly stated, PA practice under SB 697 is not "directed" by a physician. PA practice is "authorized" by the practice agreement with *supervision* being among the requirements of that agreement. A practice agreement may require "direction" but "direction" is no longer a legal requirement and so must be deleted from the regulation. Indeed, the word "directed" is not found in sections 3502, 3502.1,5, 3502.2, 3502.3, 3502.4, 3502.5, 3503, or 3503.5, the statutes that establish how PAs practice.[10] "Directed" must, for the regulation to be lawful, be deleted.

Moreover, the use of the word "agent" also must be reformed. 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: "Because … a physician assistant acts as an agent…" This must be changed to reflect and be authorized under current law.

Finally, the word "protocols" must be stricken here for the same reasons the PAB properly proposed striking references to protocols in its proposed changes to regulation section 1399.545. SB 697's exclusive baseline for determining PA practice is Business & Professions Code section

[9] It is likely the Medical Board will have to approve this regulation. Business & Professions Code section 3510 in pertinent part provides: "The board may adopt, amend, and repeal regulations as may be necessary to enable it to carry into effect the provisions of this chapter; provided, however, that the Medical Board of California shall adopt, amend, and repeal such regulations as may be necessary to enable the board to implement the provisions of this chapter under its jurisdiction." As these regulations risk PAs and physicians and surgeons working under incompatible informed consent standards, it would mean that a physician and surgeon would themselves have to obtain informed consent in every instance to ensure they would not be subject to discipline.

[10] The word "directing" in section 3502(d)(2) but in a context different than one describing a physician-PA relationship; as a limitation on PA's being able to "direct" certain visual devices.

3502 which begins, "(a) Notwithstanding any other law, a PA may perform medical services as authorized by this chapter if the following requirements are met:". Thus, if "the following conditions are met" a PA "may perform medical services as authorized by this chapter" – period, with "period" being underscored by the beginning of the sentence" "Notwithstanding any other law". Moreover, to incorrectly leave the word here but correctly propose to delete it elsewhere is, respectfully, needlessly confusing.

CAPA RESPECTFULLY SUGGESTS:

> ~~**Because physician assistant**~~ **PA** practice **is authorized in a practice agreement, under the supervision of a physician and surgeon, in accordance with Section 3502 of the Business and Professions Code. In instances where the practice agreement specifies that the PA acts as an agent for that physician and surgeon** ~~**is directed by a supervising physician, and a physician assistant acts as an agent for that physician and surgeon,**~~ the orders given and tasks performed by ~~a physician assistant~~ the PA 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~~ practice agreement ~~**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 setting, patients' residence, residential facility, and hospice, as applicable, a ~~physician assistant~~ **PA** may~~, pursuant to a delegation practice agreement~~ **perform any task, authorized by Section 3502 of the Business and Professions Code, including, but not limited to, the following:** ~~**and where present, protocols**~~**:**

Subdivision (i)(1) PAB Does Not But Must Propose Changes:

The PAB proposes not changing subdivision (i)(1) of this regulation. However, it must be changed so as not to be unlawfully and flatly inconsistent with over-riding statute. The regulation currently reads:

> (i) (1) 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.

DISCUSSION: **First**, for the reasons discussed above, the word "delegated" must be stricken.

Second, the regulation unlawfully and directly contradicts current law when it provides that a PA may perform procedures requiring anesthesia "only in the personal presence of a supervising physician." 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 between licensed professionals in a practice agreement. But the law is crystal clear on one point. Business & Professions Code section 3501(f)(1) provides: "'Supervision', as defined in this subdivision, ***shall not be construed to require the physical presence of the physician and surgeon***" (Emphasis added). This regulation unambiguously requires just such supervision, but the quoted statute specifically forbids the PAB from construing "supervision" in such a fashion. The regulation is therefore unlawful, cannot be enforced, and should properly be brought into alignment with current law.[11]

CAPA RESPECTFULLY SUGGESTS:

> (i) (1) Perform surgical procedures **as authorized by the practice agreement; which the PA is competent to perform and consistent with the PA's education, training, and experience, and rendered under the supervision of a licensed physician and surgeon in accordance with Section 3502 of the Business and Professions Code**. ~~**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.**~~

Subdivision (i)(2) PAB Does Not But Must Propose Changes:

For much the same reason the PAB must amend (i)(1) it must amend (i)(2). The regulation currently reads:

> (i)(2) A physician assistant may also act as first or second assistant in surgery under the supervision of a supervising physician. 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 and surgeon 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.

DISCUSSION: Here, the regulation specifies with (excuse the pun) surgical precision exactly the kind of supervision that is required in surgical settings: "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 and surgeon *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."

[11] PAB board staff acknowledge this being the state of the law notwithstanding that the draft regulations do not seek to strike the parts of the regulations that obviously contradict this statute: "… the Act also prohibits … the Board from requiring the physical presence of a physician and surgeon as a term or condition of a physician assistant's reinstatement, probation, or the imposition of discipline." Page 75 of PAB August 7th meeting materials.

First, as explained above, section 3501(f)(1) prohibits the PAB from construing "supervision" as requiring a physician and surgeon, in the words of the regulation, to be "physically accessible."

Second, and more broadly, PAB micromanagement of the exact nature of and conditions for the supervisorial relationships between physicians and surgeons and PAs is, post SB 697, unlawful, and contradicted by statute. Except for those enumerated restrictions on PA practice set forth in 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.* Thus, while some routine surgical procedures, such as the removal of a wart, by an experienced PA may require one level of supervision as reflected in an agreement, other kind of surgical interventions such as open-heart surgery may require closer supervision as controlled by the practice agreement and the applicable standard of care based on the PA's education, training, and experience.

In contrast, the PAB's current regulation makes no distinctions between kinds of surgeries or the experience of PAs. When it comes to surgeries, the regulation entirely removes from PAs and physicians and surgeons the ability and discretion to nuance their supervisorial relationships in practice agreements around these kinds of experience and procedure-based contingencies. The regulation is therefore unlawful.

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.

Next, the statute also provides a PA "may perform medical services" -- i.e., a *PA has a statute-based right to practice* -- "if the following conditions are met". This means that so long as the "conditions" listed in section 3502 are met, *the PA has a legal right to practice according to and under the provisions of the practice agreement and no regulation may lawfully impose additional requirements as a precondition to PA practice of any procedure beyond those listed in section 3502.* This is what is meant when President Grant correctly observes that "PAs … practice is … authorized." Indeed, when President Grant suggests altering a regulation because it is "the writing [i.e., practice agreement] which authorizes the medical services to be performed," he is correct, and the extant regulation is unlawful for this very reason. This is what SB 697 was, in fact, all about:

> [T]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.

Assembly Business & Professions Committee analysis and explanation of SB 697, July 9, 2019, p. 5 (emphasis supplied).[12]

CAPA RESPECTFULLY SUGGESTS:

> (i)(2) A physician assistant may also act as first or second assistant in surgery **as authorized by the practice agreement; which the PA is competent to perform and consistent with the PA's education, training, and experience, and rendered under the supervision of a licensed physician and surgeon in accordance with Section 3502 of the Business and Professions Code**. ~~**under the supervision of a supervising physician. 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 and surgeon 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.**~~

Subdivision (j) PAB Proposed Changes:

The draft regulations propose adding a new informed consent requirement, as follows:

> (j) A physician assistant may perform informed consent about recommended treatments. In seeking a patient's authorization or agreement to undergo a specific medical treatment the physician assistant shall:
> (1) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make independent, voluntary decision.
> (2) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The information should include:
> (A) the diagnosis;
> (B) the nature and purpose of recommended interventions; and,
> (C) the burdens, risks, and expected benefits of all options, including foregoing treatment.
> (3) Document the informed consent conversation and the patient's decision in the medical record.

DISCUSSION: First, and respectfully, this proposal comes out of the blue. No statute commands it. There is no evidence, or even discussion, in the August 7th meeting board materials that explains why it is needed; no recitation of, for example, illustrative disciplinary matters where failure of PAs to obtain informed consent has been an issue … *even once*. As a result, this proposed regulation would fail the legal requirement that regulations be "necessary."

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

OAL must review regulations for compliance with the "necessity" standard of Government Code section 11349.1. Government Code section 11349(a) defines "necessity" as meaning "...the record of the rulemaking proceeding demonstrates by ***substantial evidence*** the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. For purposes of this standard, evidence includes, but is not limited to, facts, studies, and expert opinion." (Emphasis added)

To further explain the meaning of "substantial evidence" in the context of the "necessity" standard, subdivision (b) of section 10 of title 1 of the CCR provides:

> In order to meet the "necessity" standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:
> (1) a statement of the specific purpose of each adoption, amendment, or repeal; and
> (2) information explaining why each provision of the adopted regulation is required to carry out the described purpose of the provision. Such information shall include, but is not limited to, facts, studies, or expert opinion. When the explanation is based upon policies, conclusions, speculation, or conjecture, the rulemaking record must include, in addition, supporting facts, studies, expert. opinion, or other information. An "expert" within the meaning of this section is a person who possesses special ski11 or knowledge by reason of study or experience which is relevant to the regulation in question.

The OAL does not hesitate to reject regulations on the basis of failure to provide "substantial evidence" proving their "necessity." **"**In this rulemaking action [involving the Osteopathic Medical Board], many proposed amendments to the CCR and Guidelines are not supported by substantial evidence in the rulemaking record. A number of these provisions are discussed below. The Board must resolve all necessity issues before resubmittal to OAL"[13] Indeed, in exactly the situation here, where no statute commands the issuance of this proposal, OAL scrutiny is even more exacting: **"**The absence of a statutory requirement to adopt these regulatory provisions signifies that the adoption was at the Board's discretion, and the APA requires the need for this adoption to be supported by substantial evidence in the record. The Board's purpose statement contains no such evidence; therefore, the Board failed to satisfy the necessity standard in proposing section 1663, subdivision (b)."[14]

Second, the proposal violates section 3502 for the reasons explained above. How physicians and surgeons 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.

Third, the proposed regulation confusingly varies from and partially contradicts a currently binding regulation of the Medical Board governing informed consent.[15]

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[13] https://oal.ca.gov/wp-content/uploads/sites/166/2017/05/2016-1025-04S.pdf.
[14] Ibid.
[15] See, for example, Cal. Code of Reg. Div. 1, Chap. 3.5, Ar. 4, section 784.29. *Informed Consent to Medical Treatment*.

Fourth, unlike the Medical Board's regulation, and underscoring the wisdom of permitting PAs and physicians and surgeons to shape informed consent requirements to the different situations they daily confront, the regulation would require PAs to choose between allowing a patient to die and following the regulations' dictates. The proposed regulation does not differentiate between the kind of consent and documentation required in a scheduled appointment *and the kind required in an ER when a PA confronting an unconscious patient could not obtain the kinds of consent currently required in every instance – it contains no exceptions -- by this proposed regulation.*[16]

CAPA's search of informed consent legal authorities governing health care professionals nationally has revealed no regulation or statute like the one being proposed here; one that purports both to apply to every possible kind of medical situation, but also offers no acknowledgement that the ability to obtain consent varies depending on the circumstances. The reason for this absence is simple: such a rule does not work because it places the health care professional between the rock of obeying an unwisely all-encompassing, prescriptive regulation and the hard place of doing what is needed to save a life.

CAPA RESPECTFULLY SUGGESTS:

The proposed informed consent regulation should not be a part of a formal regulatory package until the "substantial evidence" warranting it is identified and presented to the PAB, until the Medical Board is consulted, until such a regulation is carefully reconciled with existing laws governing such consent.[17]

CONCLUSION

The PAB wisely and unanimously resolved on August 7th not to proceed to formal rulemaking without having the benefit of "adverse" public input such as this letter. For the many reasons outlined above, this was a wise decision because the regulations discussed above, as currently drafted, are unlawful and unsupported and should be re-worked by the PAB prior to becoming the subject of an expensive and formal APA process.

With hope that CAPA and the PAB will always continue their collaboration on these matters of intense interest to patients, PAs, physicians and surgeons, their trade representatives, and the Legislature, I remain

[16] The Medical Board will likely have to approve this regulation.

[17] CAPA refrains here from addressing proposed regulation section 1399.546 because, on August 7th, the PAB voted to repeal the existing regulation. Likewise, CAPA refrains from addressing the proposed changes to 1399.545 because the PAB voted to withdraw it from consideration. CAPA endorses the former action of the PAB. As to the proposed changes to regulation section 1399.545, the unlawful deficiencies in that proposal extend beyond simply the arbitrary time limits that prompted its withdrawal. The requirement without exception of on-site inspections, the requirement of an ambiguous "quality assurance program" when assuring such quality is the entire aim of a practice agreement, and the requirement that PAs and physicians and surgeons must meet on a pre-set timetable with no exceptions are all contradicted by and unlawful under SB 697 and current law. PAB staff correctly recognizes that the Medical Board may have to approve changes to this regulation. *See*, materials for August 7th meeting at p. 74. As well, CAPA believes that many other conforming changes should be made to the PAB's regulations beyond those correctly proposed. That CAPA does not highlight all of those here should not, please, be taken as agreement with the broader regulatory *status quo*.

Very truly yours,

Brett Bergman, MPA, PA-C
President, California Academy of PAs

cc: The Hon. Gavin Newsom, the Hon. Lourdes M. Castro Ramírez, the Hon. Kim Kirchmeyer, the Hon. Steven Glazer, the Hon. Evan Low, the Hon. Anna Caballero