

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR DEPARTMENT OF CONSUMER AFFAIRS • PHYSICIAN ASSISTANT BOARD

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MEMORANDUM

DATE	November 6, 2023		
ТО	Physician Assistant Board (Board)		
FROM	Karen Halbo, Regulations Counsel, Attorney III Jasmine Dhillon, Legislative and Regulatory Specialist		
SUBJECT	14.B. 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 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.

Public Comment

MISSION: To protect and serve consumers through licensing, education, and objective enforcement of the Physician Assistant laws and regulations.

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.

<u>Summaries of and Proposed Responses to Public Comments</u>

In accordance with Government Code section <u>11346.9</u>, 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 are below for Board consideration and approval.

Comment from Greg Hadfield, PA-C - received 7.28.23

The Board appreciates Mr. Hadfield's comment, but beyond his assertion that "changing the regulation is not in keeping with the medical needs of the California populace, "the Board does not find his comment states a specific objection or recommendation to this rulemaking. Mr. Hadfield's comment recounts his experience working as a Dermatology PA and seems to advocate that a PA with specialized experience be able to continue working in that specialization under a practice agreement with a non-specialist physician. The proposed regulatory changes do not forbid such an arrangement. The contours of a PAs practice, by statute, is shaped by and set out in the practice agreement between the supervising physician and the PA. Since the proposed regulatory language does not require a PA to only work under physicians that have the same area of specialization as the PA, the Board declines to make any changes to this rulemaking in response to Mr. Hadfield's comment.

Comments from Todd Primack, DO, and Antonio Hernandez Conte, MD, MBA, FASA, for the California Society of Anesthesiologists (CSA) - received 9.11.23 and Charlotte Tsui, Esq., California Medical Association (CMA) – received 9.12.23

The Board appreciates the comments from CSA and CMA. The two comment letters raise similar concerns and request the removal of the proposed amendments to 16 CCR section 1399.540(d) and 16 CCR section 1399.541(i)(1)-(3).

Proposed amendments to 16 CCR section 1399.540(d)

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

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

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

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

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

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

Proposed amendments to 16 CCR section 1399.541(i)(1)

The CSA and CMA comments both request the Board remove the proposed amendments to 16 CCR section 1399.541(i)(1)-(3). The amendments to 16 CCR section 1399.541(i)(1)

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allow a PA to perform surgeries on a patient undergoing procedural sedation without the personal presence of the supervising physician and replace the requirement of the personal presence of the supervising physician when a PA is performing a surgery on a patient under general anesthesia with the requirement that the supervising physician be immediately available during the procedure. Both comments argue that allowing PAs to perform surgeries on a patient under procedural sedation or general anesthesia without the personal presence of the supervising physician is beyond the scope of PA practice after the passage of SB 697.

The CSA comment characterizes procedural sedation as "a concept created by emergency room physicians to enable intravenous general anesthesia for short procedures without the presence of anesthesiologists." CSA also provides the Board with an article from the ASA Monitor entitled "Anesthesiology Oversight for Procedural Sedation." CSA urges the Board to consider that due to the variability in sedation practices and patient responses, procedural sedation can result in loss of protective airway reflexes and spontaneous ventilation. The CMA comment asserts the proposed regulatory language is following the definition of procedural sedation in the national guidelines from the America College of Emergency Physicians (ACEP) and argues using the term "procedural sedation" makes the regulation unclear.

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

Both the CSA and CMA comments emphasize that sedation is a continuum and it is not always possible to predict how an individual patient will respond under sedation and cite to the American Society of Anesthesiologists (ASA). The CSA comment includes the ASA "Statement on Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia"). The Board has carefully reviewed the CSA and CMA comments and proposes to modify the proposed regulatory language to move how surgical procedures on a patient under procedural sedation are regulated so that those procedures are regulated in the same manner as surgery on a patient under general anesthesia. In the interests of public protection, the Board proposes modifications to the proposed language in 16 CCR section 1399.541(i)(1) that make this change.

The CSA comment includes the ASA "Statement on ASA Physical Status Classification System," and notes that assigning an ASA Physical Status classification level is a clinical decision for which PAs lack the requisite education and training to make this assessment prior to a patient submitting to surgery. The Board agrees that the determination of the patient's status and fitness for surgery is best made by a physician, and not a PA. Just as the existing regulation requires the supervising physician to review and reach a determination each time that the PA is adequately trained and qualified to perform the surgical procedure under the proposed level of sedation, the Board proposes to add language to 16 CCR section 1399.541(i)(1) that requires: "The physician assistant shall

ensure the supervising physician and surgeon has performed an assessment of whether the patient's physical status and fitness is appropriate to undergo the procedure." This modification makes clear that each time, the supervising physician must assesses the appropriateness of the PA performing the surgical procedure given the procedure involved, the patient, and the level of sedation, and the supervising physician must also assess whether the patient's physical status and fitness is appropriate to undergo the procedure under the planned level of sedation.

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

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

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

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

- "(1) Supervision, as defined in this subdivision, shall not be construed to require the physical presence of the physician and surgeon, but does require the following:
 - (A) Adherence to adequate supervision as agreed to in the practice agreement.
 - (B) The physician and surgeon being available by telephone or other electronic communication method at the time the PA examines the patient.
- (2) Nothing in this subdivision shall be construed as prohibiting the board from requiring the physical presence of a physician and surgeon as a term or condition of a PA's reinstatement, probation, or imposing discipline."

The Legislature also did not choose to include language requiring the physical presence of the supervising physician in the acute care hospital setting, instead, opting for a supervision model even in hospitals. BPC section 3502(f) states only that:

"(f) Notwithstanding any other law, a PA rendering services in a general acute care hospital as defined in Section 1250 of the Health and Safety Code shall be supervised by a physician and surgeon with privileges to practice in that hospital. Within a general acute care hospital, the practice agreement shall establish policies and procedures to identify a physician and surgeon who is supervising the PA."

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

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

Under BPC section 3502.3, the supervising physician must provide adequate supervision commensurate to the type of medical services being provided by the PA. This is intended to protect the public by requiring the supervising physician to consider the appropriate supervision for each delegated task. This also incentivizes the supervising physician to make clear in the practice agreement the policies and

procedures that must be followed for a PA to perform various medical services. The Board has not found supervising physicians are allowing PAs to perform procedures beyond the PA's level of training and experience. While the Board understands CSA's and CMA's stances that "personal presence" of the supervising physician is required for every surgery involving general anesthesia or procedural sedation, the Board does not agree that this is true in all circumstances.

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

The supervising physician who is ultimately responsible for the patient must decide whether their personal presence is what constitutes appropriate supervision for a particular surgery by a PA on a patient. A supervising physician is always able to state in the practice agreement when their personal presence is required for a PA to perform surgery. The Board declines to require the "personal presence" of the supervising physician in regulation in contravention to the express language in BPC section 3501(f)(1). The Board believes the proposed regulatory changes, as modified, strike an appropriate balance between public protection and the statutory changes made with the passage of SB 697.

Proposed amendments to 16 CCR section 1399.541(i)(2) and (3)

The CSA and CMA comments do not raise any specific objections to the proposed non-substantive change to 16 CCR section 1399.541(i)(2) and (3). The change to those two paragraphs is graphic in nature, moving the last sentence of 16 CCR section 1399.541(i)(2) to stand alone as 16 CCR section 1399.541(i)(3). The definition was not changed. The objections raised are to when "immediately available" supervision is allowed, but not to the definition itself. The change made in the proposed amendments was non-substantive, and the Board does not see a need to make changes to revise 16

CCR section 1399.541(i), paragraphs (2) and (3).

Action Requested

Please review the attached public comments and proposed Modified Text, the attached reports on SB 697, and the summary and proposed responses to comments set forth above. If the Board agrees with the proposed responses to comments and the proposed Modified Text, please entertain a motion to adopt the proposed responses to comments and the Modified Text and direct staff to send the Modified Text and an Availability of Documents Added to the Rulemaking File Notice out for a 15-day public comment period. If no public comments are received on the 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.

- Attachment: 1. Proposed Modified Text
 - 2. Greg Hadfield's 7.28.23 public comment email
 - 3. California Society of Anesthesiologists 9.11.23 comment letter and attachments
 - 4. California Medical Association 9.12.23 comment letter
 - 5. April 18, 2019, Senate Business, Professions and Economic Development report on SB 697
 - 6. May 18, 2019, Senate Floor Analysis on SB 697
 - 7. July 8, 2019, Assembly Committee Business and Professions Analysis on SB 697
 - 8. September 9, 2019, Senate Floor Analysis on SB 697

Attachment 1

DEPARTMENT OF CONSUMER AFFAIRS Title 16. PHYSICIAN ASSISTANT BOARD

PROPOSED MODIFIED TEXT SB 697 Implementation

Legend:	Added text is indicated with an <u>underline</u> .		
	Omitted text is indicated by (* * * *)		
	Deleted text is indicated by strikeout.		
	Modified added text is indicated with a double underline.		
	Modified deleted text is indicated by double strikeout.		
	All modifications are also <mark>yellow-highlighted</mark>		

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.
- (<u>ce</u>) "Approved program" means a program for the education and training of physician assistants which has been approved by the <u>bB</u>oard.
- (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.
- (dg) "Approved controlled substance education course" means an educational course approved by the bBoard 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 servicespractice 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 <u>bB</u>oard or <u>Medical Board of California or their its</u> representative may require proof or demonstration of competence from any physician assistant for any tasks, procedures, or management <u>he or she isthey are</u> 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 or diagnostic problem exceeds their own physician assistant 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 facilityies, and hospices, 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 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 when 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 earingproviding 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) 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 hertheir 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

From: Greg Hadfield

To: Dhillon, Jasmine@DCA

Subject: Comment on proposed changes to SB 697

Date: Friday, July 28, 2023 10:03:47 PM

This Message Is From an Untrusted Sender

Warning: This email originated from outside of the organization! Do not click links, open attachments, or reply, unless you recognize the sender's email.

Report Suspicious

I feel that the changing of the regulation is not in keeping with the medical needs of the California populace. My experience as a Dermatology physician assistant has been both covered by a supervising board-certified dermatologist, and by a supervising physician without a dermatology, specialty credential, and does not fully know my skills or procedure or diagnostic levels, because they are not dermatology trained. I followed the letter of the law to provide standard of care and best medical practices that any dermatology provider would do so, and have yet to have any questions to my ability in Dermatology be challenged by my treatment due to bmy experience. Physician assistants that are initially trained by Dermatology Physicians, or have the extent of experience and the specialty under any Physician are more than Adequate to continue practice with the supervision of a non-dermatology provider who can advise on emergent conditions. I need to see more studies that show dermatology trained physician assistants initially trained under a board-certified dermatologist initially have been more negligent and negligent in their standard of care or best medical practices. I feel that with my experience under both systems, and currently being under a board-certified dermatologist who's also a Mohs certified surgeon has been comfortable, but I very seldom asking for advice, most likely due to my experience, that this is a hurdle that does not need to be placed in front of a specialty that has so many holes and gaps in provision, for all of the patients in California.

Sincerely, Greg Hadfield, PA-C Sent from phone

Attachment 3



September 11, 2023

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

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

RE: Proposed Rulemaking Concerning Implementation of SB 697

Dear Ms. Dhillon:

On behalf of the California Society of Anesthesiologists (CSA), and our over 3,000 anesthesiologists, we respectfully submit these written comments to the Physician Assistant Board (hereafter; Board) regarding the Proposed Rulemaking Concerning Implementation of SB 697.

Anesthesiologists are guardians of patient safety in the operating room, in the delivery room, in the intensive care unit, in pain management clinics, and on the frontlines of the COVID-19 pandemic. Anesthesiologists are medical doctors that undergo over 12 years of education and training to navigate critical life-and-death moments in the operating room and multiple procedural areas. They also provided and continue to provide emergency services and served as airway management experts for the sickest of patients diagnosed with and suffering from COVID-19.

Bottom line, anesthesiologists are leaders in safe utilization and administration of sedation and all forms of anesthesia, whether caring for COVID-19 patients, managing a crisis during surgery or labor and delivery, or providing pain management services.

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.

(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 any task, procedure, or diagnostic problem exceeds their own level of competence, they shall either consult a supervising physician and surgeon, or refer the patient to a licensed healthcare provider competent to render the services needed for the task, procedure, or diagnosis.

Question(s): What safeguards are in place to prevent a physician assistant from referring to another physician assistant or a nurse practitioner with independent practice status?

Comment(s): CSA strongly recommends that the Board revert to the existing regulations where the physician assistant must "refer such cases to a physician." The option of the physician assistant to "refer the patient to a licensed healthcare provider competent to render the services needed for the task, procedure, or diagnosis" is *NOT* authorized under SB 697 (Chapter 707, Statutes of 2019) and would constitute an underground regulation that will be challenged at the Office of Administrative Law.

It is virtually impossible to determine what tasks, procedures, or diagnostic problems exceed a physician assistant's competency. This is another classic example of "they don't know what they don't know." In those

instances, where the physician assistant is clearly acting as an agent of their supervising physician, the referral must be to another physician with specialty expertise in the condition of the patient. (This is the way physicians and surgeons practice.) CSA understands the Initial Statement of Reasons issued by the Board, and recognizes that there are certainly instances where a physician assistant may be compelled to refer the patient to a dentist, podiatrist, psychologist, or therapist et al. However, nothing would prevent a physician assistant who is unable to effectively handle the patient's needs from referring to another physician assistant who may also not be competent to render the services. Furthermore, nothing would prevent a physician assistant from referring a patient to a nurse practitioner with independent practice status.

Arguably, if a physician assistant can determine that a patient presents with a condition that exceeds their own level of competency, how are they able to determine the competency of another licensed healthcare provider? If an instance exceeds the competency of a physician assistant, a referral to a physician must be required so the physician may ascertain where and by whom follow-up services shall be provided.

Physicians undergo years of training, making them prepared and qualified to handle unexpected findings. A physician is trained to recognize some medical issues may be linked to prior medical or surgical conditions that may be interrelated. Even seemingly routine surgical procedures can result in complications leading to patient deaths. The extensive medical education and clinical experience of a physician ensures they can manage the medical emergencies that may arise during routine procedures.

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.

- (i)(1) Perform surgical procedures without the personal presence of the supervising physician which are customarily performed under local anesthesia <u>or procedural sedation</u>. Prior to <u>a physician assistant</u> <u>performing delegating any such</u> surgical procedures <u>under local anesthesia</u>, procedural <u>sedation</u>, or <u>general anesthesia</u>, the supervising physician shall review <u>the evidence documentation</u> which indicates that the physician assistant is trained <u>and qualified</u> to perform the surgical procedures. <u>All other s Surgical procedures</u> requiring <u>other forms of general</u> anesthesia may be performed by a physician assistant only <u>when</u> in the <u>personal presence of</u> a supervising physician <u>is immediately available during the procedure</u>.
- (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.

Question(s): Where is the specific reference and authorization under SB 697 (Chapter 707, Statutes of 2019) for a physician assistant to perform surgical procedures under "procedural sedation" either with or without the "personal presence" of the supervising physician? Where is the specific reference and authorization under SB 697 (Chapter 707, Statutes of 2019) for a physician assistant to perform surgical procedures under "general anesthesia" with or without the supervising physician being "immediately available during the procedure?"

Comment(s): CSA strongly recommends that the Board revert to the existing regulations where the physician assistant shall *ONLY* perform surgical procedures without the personal presence of the supervising physician that are customarily performed under local anesthesia. Furthermore, these regulations do not define "procedural sedation" nor was that term defined under SB 697 (Chapter 707, Statutes of 2019). The enabling legislation that precipitated this regulatory package *NEVER* referenced nor considered the method and manner by which surgical procedures would be performed by a physician assistant requiring general anesthesia.

In fact, as introduced on February 22, 2019, this legislation included a provision under SEC. 3, Business and Professions Code Section 3502, Subsection (a)(2)(F) authorizing a physician assistant to perform certain tasks such as, "Performing surgical procedures that are customarily performed under local anesthesia or other forms of sedation that allow a patient to maintain the patient's own airway, and act as first or second assistant in surgery requiring other forms of anesthesia." That provision was specially struck from the bill as amended on April 10, 2019. Therefore, these deletions and additions would constitute underground regulations that will be challenged at the Office of Administrative Law.

Physician assistants are not qualified to perform surgery on patients undergoing procedural sedation or general anesthesia. If a medical or surgical emergency occurs there may not be enough time to call for help. A surgeon is trained to care for all complications for all procedures they undertake, and this cannot be consistently said for physician assistants who undertake surgical or interventional procedures.

Surgeons often refer to anesthesiologists as the last hurdle to clear before surgery. Anesthesiologists respect the risk of general anesthesia, and the associated increased risk based on the surgical procedure and patient's medical condition. Anesthesiologists facilitate trained surgeons' ability to perform necessary procedures – both simple and complex. However, it should not be used to enable minimally trained physician extenders to perform surgery beyond the standard of care.

Procedural sedation is a concept that was created by emergency physicians to enable intravenous general anesthesia for short procedures without the presence of anesthesiologists. Because of the significant variability that may exist in sedation practices and the continuum of sedation that may lead to loss of protective airway reflexes and spontaneous ventilation (i.e., patient preparation and monitoring, practitioner education and training, oversight of quality and safety in provided care), procedural sedation place patients, practitioners, and health systems at risk. This regulation would create an unnecessary additional risk by allowing a physician assistant who is not adequately trained to manage medical emergencies to perform a surgical procedure on a patient undergoing this risky form of sedation.

To address the risks inherent with procedural sedation, safeguards must be in place to ensure patient safety and regulatory compliance for the facility or site of service. This requires a comprehensive and consistent set of policies, procedures, and documentation. It is inappropriate to intentionally utilize an anesthetic technique for a patient which removes safeguards for elective procedures or surgeries.

There are countless opportunities where oversight of the procedural sedation policies and procedures can enhance patient safety, including:

- Monitoring as recommended by the *American Society of Anesthesiologists Standards for Basic Anesthesia Monitoring*, including capnography (i.e., carbon dioxide) and pulse oximetry?
- Use of a universal preprocedural checklist, "time out safety check" before the beginning of the procedure, and sign-out at the end of the procedure.
- "Stop the line" culture where all members of the team can speak up and express concerns regarding the patient, equipment, or the procedure.
- Monitoring safety events and conducting a nonpunitive event review, and identifying lessons learned that should be disseminated to all team members to avoid similar potential future events.
- Involvement of an anesthesiologist to perform pre-operative evaluation to determine appropriateness of
 the patient for the procedure and manage medicating, monitoring, airway management, and rescuing the
 patient if needed.
- Post-procedure management with 1:1 trained recovery room nurse for the immediate post-operative recovery for at least 30 minutes with complete recovery of preoperative status. If a reversal agent, such as Naloxone or Flumazenil is administered, additional dedicated recovery time should be routine.

All these safeguards address the complexity and potential risks of procedural sedation and demonstrate that these procedures require the medical expertise of a trained physician, not a physician assistant. Therefore, without a minimum of these oversight protections regarding procedural sedation and without the personal presence of the supervising physician, physician assistants should *NOT* be performing surgery under procedural sedation.

Outside of procedural sedation, anesthesia and sedation are also complex and can result in medical emergencies that should be handled by a physician, not a physician assistant. According to the American Society of Anesthesiologists because sedation is a continuum, it is not always possible to predict how an individual patient will respond under sedation.¹¹

This fact requires that surgical procedures where a patient is undergoing procedural sedation or general anesthesia are performed by physicians who have the medical training to manage any potentially life-threatening emergency that arise if the patient enters an unintended deeper level of sedation. Having a physician "immediately available" is not sufficient to protect safety during these procedures.

Physician assistants lack the appropriate education, training, credentials, and clinical decision making to assess the level of patient complexity that can exist prior to a patient submitting to surgery. Prior to even considering whether a patient is a safe candidate for surgery, especially those requiring general anesthesia, and the appropriate site of service for that procedure, an anesthesiologist should determine the physical status of the patient.

The ASA Physical Status Classification System has been in use for over 60 years. The purpose of the system is to assess and communicate a patient's pre-anesthesia medical co-morbidities. The classification system alone does

not predict the perioperative risks, but used with other factors (i.e., type of surgery, frailty, level of deconditioning), it can be helpful in predicting perioperative risks.

Assigning an ASA Physical Status classification level is a clinical decision based on multiple factors. While the ASA Physical Status classification may initially be determined at various times during the preoperative assessment of the patient, the final assignment of ASA Physical Status classification is made on the day of anesthesia care by the anesthesiologist after evaluating the patient.

The definitions and examples below are guidelines for the clinician. To improve communication and assessments at a specific institution, anesthesiology departments and other sites of service may choose to develop institutional-specific examples to supplement the American Society of Anesthesiologists-approved examples.

- **ASA I:** A normal healthy patient. For example, healthy, non-smoking, and no or minimal alcohol use, etc.
- **ASA II:** A patient with mild systemic disease. For example, mild diseases only without substantive functional limitations, current smoker, social alcohol drinker, pregnancy, obesity controlled, and mild lung disease, etc.
- **ASA III:** A patient with severe systemic disease. For example, substantive functional limitations, one or more moderate to severe diseases, morbid obesity, hepatitis, alcohol dependence or abuse, implanted pacemaker, and undergoing regularly scheduled dialysis, etc.
- **ASA IV:** A patient with severe systemic disease that is a constant threat to life. For example, ongoing cardiac ischemia or severe valve dysfunction, etc.
- **ASA V:** A moribund patient who is not expected to survive without the operation. For example, ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction, etc.
- ASA VI: A declared brain-dead patient whose organs are being removed for donor purposes.

According to the Initial Statement of Reasons that accompanied this regulatory package there was acknowledgment by the Board of investigating a complaint that a patient died while a physician assistant was performing a procure under general anesthesia.

"This proposal seeks to clarify the level of supervision that must be agreed to between a PA and a supervising physician who has a PA perform surgical procedures on patients under general anesthesia. The Board investigated a complaint where the PA was performing surgery on a patient under general anesthesia and something went wrong. Because the supervising physician was not immediately available to return and assist, the patient died. Allowing a PA to perform surgical procedures on a patient under general anesthesia without requiring the supervising physician to be immediately available during the procedure would create an untenable risk to the lives and health of California consumers. The proposed language does not require the physical presence of the supervising physician."

Therefore, even the "immediately available" standard for the supervising physician in these instances is *NOT* appropriate nor within the standard of care for these procedures. Therefore, CSA strongly recommends that these additions regarding "general anesthesia" be struck from the regulations or require the "personal presence" of the

supervising physician when a physician assistant is performing surgery on a patient under general anesthesia. Patients can undergo major life-threatening complications during surgery that could only take a matter of seconds and/or minutes to kill a patient.

For all the reasons and references mentioned herein, CSA strongly urges the Board to consider these comments to ensure patient safety and consumer protection when Californians undergo procedures requiring sedation and anesthesia.

Thank you for your consideration of these comments. If you have any questions or require additional information, please contact CSA Legislative Advocate Bryce Docherty at (916) 769-0573 or bdocherty@tdgstrategies.com.

Sincerely,

Todd Primack, DO

Chair, CSA Legislative and Practice Affairs Division

Antonio Hernandez Conte, MD, MBA, FASA

President, California Society of Anesthesiologists

(Attachments)

Conty MD, MBA

ⁱ ASA Monitor. Anesthesiology Oversight for Procedural Sedation. November 2022; pages 26-27

ii American Society of Anesthesiologists. Position on Monitored Anesthesia Care. Last amended on October 23, 2019

iii https://www.asahq.org/standards-and-practice-parameters/statement-on-asa-physical-status-classification-system



Attachment:

ASA Monitor. *Anesthesiology Oversight for Procedural Sedation*. November 2022; pages 26-27

Workforce Hot Buttons

Anesthesiology Oversight for Procedural Sedation

Basem B. Abdelmalak, MD, FASA, SAMBA-F

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riven by advances in minimally invasive diagnostic and therapeutic procedures, the demand for anesthesia and procedural sedation outside the OR has expanded more rapidly than ever. This has placed tremendous strain on anesthesiology departments, both to fulfill anesthesia service needs and to oversee procedural sedation. Nonoperating room anesthesia (NORA) is an extension of OR anesthesiology practice, either personally performed, medically directed, or nonmedically directed. Separate from the extension of anesthesiology services to NORA settings is the procedural sedation performed by nonanesthesiologist providers in many procedural units. Because of the significant variability that may exist in sedation practices (e.g., patient preparation and monitoring, practitioner education and training, oversight of quality and safety in provided care), procedural sedation may place patients,

practitioners, and health systems at risk. Whether or not the anesthesiology department fully embraces the role, physician anesthesiologists are responsible for patient safety and regulatory compliance everywhere procedural sedation is performed.

In 2009, The Centers for Medicare & Medicaid Services (CMS) issued the §482.52 Condition of Participation. CMS states that the director of anesthesia services is responsible for all anesthesia services throughout the hospital, including all departments in all campuses and offsite locations where anesthesia services are provided. The directive applies to all moderate and deep procedural sedation services (Table 1) provided by nonanesthesiologist proceduralists (asamonitor. pub/3Lu9m3f; asamonitor.pub/3DCUsG9; asamonitor.pub/3xBk3vl). Moderate sedation is typically provided by a nonanesthesiologist physician proceduralist who is also performing the procedure and a sedation nurse. Deep sedation involves than initially intended.

two nonanesthesiologist physician proceduralists – one administers and monitors deep sedation while the other performs the procedure. While the oversight includes both moderate and deep sedation, efforts (and this overview) are generally focused on moderate sedation, as it constitutes almost all the proceduralist-provided sedation services (99.8% vs. 0.2% of total sedation cases, respectively, at the author's Cleveland Clinic institution) (Anesth Analg 2022;135:198-208). Of note, in developing the Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/ Analgesia, ASA has recognized that sedation is a continuum, and it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to provide a given level of sedation should be able to rescue patients whose level of sedation becomes deeper



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The first principle in addressing procedural sedation is to set priorities. The first is to ensure patient safety. The second priority is to ensure regulatory compliance for the facility, which requires a comprehensive and consistent set of policies and documentations. The third priority is to facilitate efficient and easy workflows for staff and patients - facilitating practice and eliminating unnecessary documentation burdens whenever possible. Problems occur when the third priority (production pressure) threatens to usurp the first two $\frac{7}{8}$

Different facilities and their anesthesiology departments have adopted their own version/structure of meeting CMS procedural oversight mandates. A first step in implementing such oversight is to identify when and where procedural sedation occurs. Until you start looking, you probably don't know. Throughout the hospital, opioids and/or benzodiazepines are given to patients to treat pain and/ or anxiety. That alone is not considered procedural sedation; however, when these medications are used to facilitate a procedure, then procedural sedation safety and regulatory parameters need to be applied to protect the patient. The reason is because the intent of the medication is to suppress an anxious patient to tolerate a painful procedure. Prior consent and additional monitoring throughout are required to protect patients after they lose their in-

Table 1: Differences Between Moderate and Deep Procedural Sedation						
Comparison Item	Moderate Sedation	Deep Sedation				
Responsiveness	Purposeful response to verbal or tactile stimuli	Purposeful response to painful stimulus				
Airway	No airway support intervention is required	Airway support intervention may be required				
Spontaneous ventilation	Adequate	May not be adequate				
Hemodynamics	Remains stable	Remains stable				
Privilege requirements	Physicians should be trained and judged to be able to provide the service safely	Physicians should be trained and judged to be able to provide the service safely				
	Biannual ACLS and online sedation course certification required	Biannual ACLS and online sedation course certification required				
	Biannual airway training course encouraged	Biannual airway training course required				
Personnel	Nonanesthesiologist physician proceduralist and a sedation RN	Two nonanesthesiologist physician proceduralists				
Prevalence The most commonly used sedation level by nonanesthesiologist proceduralists		Rarely used sedation level by nonanesthesiologist proceduralists				
Most commonly used medications	Benzodiazepines (e.g., midazolam) and narcotics (e.g., fentanyl)	Same as medications for moderate sedation, and/or low-dose anesthetics (e.g., propofol				
	No anesthetics (e.g., propofol, ketamine, or etomidate) allowed	or ketamine)				

Abbreviations: ACLS, advanced cardiovascular life support; RN, registered nurse.

Adapted with permission from: Abdelmalak BB, Adhami T, Simmons W, Menendez P, Haggerty E, Troianos CA. A Blueprint for Success: Implementation of the Center for Medicare & Medicaid Services Mandated Anesthesiology Oversight for Procedural Sedation in a Large Health System (Anesth Analg 2022;135:198-208).

trinsic protective faculties and until they regain their baseline status.

A recently proposed comprehensive oversight program suggested the following structure that could be scaled and modified for use within health systems to meet a hospitals' size and needs based on the communities they serve (*Anesth Analg* 2022;135:198-208). A comprehensive oversight program can provide several advantages, as highlighted in Table 2.

Procedural sedation policy

Procedural sedation oversight programs typically start with review of available local policies related to procedural sedation, involving stakeholders, and consolidating those into one comprehensive policy that establishes the standard for procedural sedation services at all sites. Ideally, the policy should aim at meeting local needs, but be based on nationally recognized guidelines and standards and state laws and regulations (J Healthc Risk Manag 2013;33:3-10; asamonitor.pub/3lq2jgi; asamonitor. pub/3Lu9m3f). Complicating the picture, while almost all national professional societies agree with the ASA principles on procedural sedation guidelines, a couple societies have disagreements. For example, the American College of Emergency Physicians does not agree with ASA on preprocedural fasting requirements, and the American Society of Gastrointestinal Endoscopy does not agree with the ASA requirement for capnography monitoring (Ann Emerg Med 2014;63:247-58; asamonitor.pub/3SjkRgf; asamonitor.pub/3mRrUOX; Anesthesiology 2018;128:437-79).

Procedural sedation committee

The next step involves inviting representation from all providers involved in the provision of procedural sedation, including but not limited to medical directors, quality improvement officers, nurse managers, and quality directors to form a multidisciplinary procedural sedation committee led by the director of anesthesia services

or their designee. This committee should meet on a regular basis to discuss and update policies, clinical topics, practice and documentation compliance, survey readiness activities, and quality events issues.

The initial "resistance" to the oversight structure generally disappears as proceduralists and sedation nurses recognize the value it provides (Table 2) in the form of education, improving patient safety, improving regulatory compliance and thus successful surveys, improving the procedural sedation team functionality, updating related policies, resolving challenges, and improving operational efficiency.

Procedural sedation locations

There should be a process for credentialing a new procedural sedation service location/unit and site visits to existing and functioning sites to ensure continued safe and compliant practice. It's important to recognize that the location often includes implicit availability of support in the form of staff, expertise, and resources to manage complications. Consequently, individual proceduralists who may be safe to perform a procedure under sedation in one location may not have that privilege in a location that has less backup.

Procedural sedation privileging and education

The director of anesthesia services has an opportunity to enhance the procedural sedation services by providing local education opportunities for the proceduralists as the need arises. There are also nationally available online courses such as the one provided by ASA (asahq.org/educationand-career/educational-and-cme-offer ings/safe-sedation-training---moderate). Setting criteria for training, education, and rescue capabilities, as well as providing physician sedation privileges, are important functions of the director of anesthesia services. Additionally, procedural sedation education and competencies for sedation RNs should be directed under the oversight of the director of anesthesia

services in collaboration with nursing education professionals.

Safety, quality, and outcomes

There are countless opportunities where the procedural sedation oversight can enhance patient safety, including:

- Introduction and application of capnography monitoring as recommended by the ASA Standards for Basic Anesthesia Monitoring (asamonitor.pub/3mRrUOX).
- Use of a universal preprocedural checklist, time out before the beginning of the procedure, and sign-out at the end of the procedure.
- "Stop the line" culture where all members of the team can speak up and express concerns regarding the patient, equipment, or the procedure.
- Monitoring safety events and conducting a nonpunitive event review, and identifying lessons learned that should be disseminated to all team members to avoid similar potential future events.

Patients and professional satisfaction

Procedural sedation case cancellation is a common challenge in some procedural areas, mostly due to medical issues such as severe comorbidities, concomitant medications, anticoagulation issues, or lack of proper optimization evident on the day of the procedure. The director of anesthesia services can provide education to identify clinical situations that can be addressed locally through proper consultations for optimization. Moreover, they can provide guidance on identifying high-risk patients who would not be proper candidates for procedural sedation and would require a higher level of care with the anesthesiology team. This has the potential to improve patient and team satisfaction and improve operational efficiencies.

Recovery and discharge criteria should be standardized and communicated, and proper education should be offered, including not allowing patients to drive after receiving procedural sedation.

Regulatory compliance

Anesthesiology oversight will help health systems and hospitals meet the required CMS mandates, which are also followed by accreditation organizations, such as The Joint Commission, and state regulations (asamonitor.pub/2YfqTby). State surveyors can conduct onsite surveys for both CMS and the state as well as a complaint survey. Procedural sedation is a high-risk activity, very commonly evaluated by most surveys. A compendium of relevant material is available from ASA on sedation policies for nonanesthesiologist providers (asamonitor.pub/3qX98bE).

Documentation in procedural sedation is an area for improvement for most programs; use of an electronic medical record when feasible would make standardization, as well as auditing, possible. It can be helpful for the committee to organize informal internal surveys that can identify problems in advance. Additionally, the internal survey process often provides a useful mechanism to support local practices and to build relationships.

Aligning patient safety with a financially viable practice

Procedural sedation has grown substantially. A data set representing one-sixth of the discharges in the U.S. showed that between 2012 and 2015, 500,000 patients had undergone inpatient interventional radiologic procedures with moderate sedation (Radiology 2019;292:702-10). A single center reported an annual 100,000 cases (Anesth Analg 2022;135:198-208). While you and I wish to benefit all those procedural sedation patients with anesthesiologist-led care, it is recognized to be impossible given the size of this service, as highlighted above, and the current workforce shortages. Since many of these procedures will continue to be provided under procedural sedation services, we have an opportunity to make an impact and enhance patient safety by raising the safety standards and also providing proper triaging skills to direct those patients who are not considered proper candidates for procedural sedation to benefit from anesthesiologist-led care. This helps our patients, health systems, hospitals, and communities in general.

Procedural sedation oversight is costly and requires resources and personnel. Moreover, it is a CMS mandate and directly impacts the hospital accreditation status as well as patient safety and the overall cost of care. Therefore, resources needed for this oversight should be provided to the director of anesthesia services to implement this comprehensive oversight. Such funds should be adequate to cover the expenses incurred by the time and effort of the director of anesthesia services and other members of the procedural sedation committee. Health systems, hospitals, and other stakeholders should request and lobby to establish an additional billing item attached to procedural sedation codes that would pay for the anesthesiology oversight efforts. In the meantime, hospitals, not anesthesiology departments, should cover those expenses.

The anesthesiology mandated oversight for procedural sedation is an important patient safety and quality-of-care issue, as highlighted by CMS' Condition of Participation. It behooves us to embrace this mandate and provide much-needed leadership in our health systems and hospitals. This includes advocacy for the necessary funds and resources to support the director of anesthesia services and to implement and maintain an effective comprehensive procedural sedation oversight program.

Disclosure: Dr. Abdelmalak is a consultant for the Acacia Foundation and a CME speaker for Medtronic USA, Inc.

Table 2: Benefits of Procedural Sedation Oversight

Improved safety of care

Improved patient and team satisfaction

Avoidance of complications (resulting in cost savings and potential litigations)

Appropriate pre-procedural consultations with other specialists (e.g., pulmonologists and cardiologists)

Increased operational efficiency

Appropriate referrals for anesthesia care

Meeting the CMS Condition of Participation mandate and other regulatory compliance parameters

Adapted with permission from: Abdelmalak BB, Adhami T, Simmons W, Menendez P, Haggerty E, Troianos CA. A Blueprint for Success: Implementation of the Center for Medicare and Medicaid Services Mandated Anesthesiology Oversight for Procedural Sedation in a Large Health System (*Anesth Analg* 2022;135:198-208).



Attachment:

American Society of Anesthesiologists. *Position on Monitored Anesthesia Care.* Last amended on October 23, 2019



Statement on Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia

Developed By: Committee on Quality Management and Departmental Administration

Last Amended: October 23, 2019 (original approval: October 13, 1999)

	Minimal Sedation Anxiolysis	Moderate Sedation/ Analgesia ("Conscious Sedation")	Deep Sedation/ Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia ("Conscious Sedation") is a drug-induced depression of consciousness during which patients respond purposefully** to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

* Monitored Anesthesia Care ("MAC") does not describe the continuum of depth of sedation, rather it describes "a specific anesthesia service performed by a qualified anesthesia provider, for a diagnostic or therapeutic procedure." Indications for monitored anesthesia care include "the need for deeper levels of analgesia and sedation than can be provided by moderate sedation (including potential conversion to a general or regional anesthetic."

Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully** following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced

^{**} Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue*** patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia ("Conscious Sedation") should be able to rescue*** patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue*** patients who enter a state of General Anesthesia.

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

*** Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.

1 American Society of Anesthesiologists. Position on Monitored Anesthesia Care. Last amended on October 17, 2018.

Last updated by: Governance

Date of last update: October 23, 2019



Attachment:

American Society of Anesthesiologists. *Statement on ASA Physical Status Classification System.* Last amended on December 13, 2020



Statement on ASA Physical Status Classification System

Developed By: Committee on Economics

Last Amended: December 13, 2020 (original approval: October 15, 2014)

The ASA Physical Status Classification System has been in use for over 60 years. The purpose of the system is to assess and communicate a patient's pre-anesthesia medical co-morbidities. The classification system alone does not predict the perioperative risks, but used with other factors (eg, type of surgery, frailty, level of deconditioning), it can be helpful in predicting perioperative risks.

The definitions and examples shown in the table below are guidelines for the clinician. To improve communication and assessments at a specific institution, anesthesiology departments may choose to develop institutional-specific examples to supplement the ASA-approved examples.

Assigning a Physical Status classification level is a clinical decision based on multiple factors. While the Physical Status classification may initially be determined at various times during the preoperative assessment of the patient, the final assignment of Physical Status classification is made on the day of anesthesia care by the anesthesiologist after evaluating the patient.

Current Definitions and ASA-Approved Examples

ASA PS Classification	Definition	Adult Examples, Including, but not Limited to:	Pediatric Examples, Including but not Limited to:	Obstetric Examples, Including but not Limited to:
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use	Healthy (no acute or chronic disease), normal BMI percentile for age	
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Current smoker, social alcohol drinker, pregnancy, obesity	Asymptomatic congenital cardiac disease, well controlled dysrhythmias, asthma without exacerbation, well controlled epilepsy, non-insulin dependent diabetes mellitus, abnormal BMI	Normal pregnancy*, well controlled gestational HTN, controlled preeclampsia without severe features, diet-controlled gestational DM.

3

ASA III

A patient with severe systemic disease Substantive functional limitations: One or more moderate to severe diseases. Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, history (>3 months) of MI, CVA, TIA, or CAD/stents.

Uncorrected stable congenital cardiac abnormality, asthma with exacerbation, poorly controlled epilepsy, insulin dependent diabetes mellitus, morbid obesity, malnutrition, severe OSA, oncologic state, renal failure, muscular dystrophy, cystic fibrosis, history of organ transplantation, brain/spinal cord malformation, symptomatic hydrocephalus, premature infant PCA <60 weeks, autism with severe limitations, metabolic disease, difficult airway, long term parenteral nutrition. Full term infants <6 weeks of age.

Preeclampsia with severe features, gestational DM with complications or high insulin requirements, a thrombophilic disease requiring anticoagulation.

ASA IV

A patient with severe systemic disease that is a constant threat to life Recent (<3 months) MI, CVA, TIA or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, shock, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis Symptomatic congenital cardiac abnormality, congestive heart failure, active sequelae of prematurity, acute hypoxicischemic encephalopathy, shock, sepsis, disseminated intravascular coagulation, automatic implantable cardioverter-defibrillator, ventilator dependence, endocrinopathy, severe trauma, severe respiratory distress, advanced oncologic state.

Preeclampsia with severe features complicated by HELLP or other adverse event, peripartum cardiomyopathy with EF <40,

uncorrected/decompensated heart disease, acquired or congenital.

ASA V

A moribund patient who is not expected to survive without the operation

Ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction

Massive trauma, intracranial hemorrhage with mass effect, patient requiring ECMO, respiratory failure or arrest, malignant hypertension, decompensated congestive heart failure, hepatic encephalopathy, ischemic bowel or multiple organ/system dysfunction.

Uterine rupture.

ASA VI

A declared brain-dead patient whose organs are being removed for donor purposes * Although pregnancy is not a disease, the parturient's physiologic state is significantly altered from when the woman is not pregnant, hence the assignment of ASA 2 for a woman with uncomplicated pregnancy.

**The addition of "E" denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

References

For more information on the ASA Physical Status Classification system and the use of examples, the following publications are helpful. Additionally, in the reference section of each of the articles, one can find additional publications on this topic.

- 1. Abouleish AE, Leib ML, Cohen NH. ASA provides examples to each ASA physical status class. *ASA Monitor* 2015; 79:38-9 http://monitor.pubs.asahq.org/article.aspx?articleid=2434536 □
- 2. Hurwitz EE, Simon M, Vinta SR, et al. Adding examples to the ASA-Physical Status classification improves correct assignments to patients. *Anesthesiology* 2017; 126:614-22
- 3. Mayhew D, Mendonca V, Murthy BVS. A review of ASA physical status historical perspectives and modern developments. Anaesthesia 2019; 74:373-9
- 4. Leahy I, Berry JG, Johnson C, Crofton C, Staffa S, Ferrari LR. Does the Current ASA Physical Status Classification Represent the Chronic Disease Burden in Children Undergoing General Anesthesia? Anesthesia & Analgesia, October 2019;129(4):1175-1180
- 5. Ferrari L, Leahy I, Staffa S, Johnson C, Crofton C, Methot C, Berry J. One Size Does Not Fit All: A Perspective on the American Society of Anesthesiologists Physical Status Classification for Pediatric Patients. Anesthesia & Analgesia, June 2020;130(6):1685-1692
- 6. Ferrari LR, Leahy I, Staffa SJ, Berry JG. The Pediatric Specific American Society of Anesthesiologists Physical Status Score: A Multi-center Study. Anesth Analg 2021 March; 132:807-817. PMID: 32665468

Last updated by: Governance

Date of last update: December 13, 2020

Attachment 4



September 12, 2023

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

Sent via email to <u>jasmine.dhillon@dca.ca.gov</u>

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 amendments to the proposed regulations implementing the statute adopted by SB 697.

CMA supported SB 697 in 2019 in order to create a more flexible practice agreement between physicians and physician assistants and to better reflect how physician assistants were being utilized within integrated settings.

CMA offers recommendations to the Physician Assistant Board ("Board") to advance our common goals of ensuring patient safety and consumer protection. Adoption of our suggestions for maintaining existing regulatory standards for referrals and surgical procedures align with our shared commitment to patients.

Physician Assistant Referrals: Changes to 16 CCR §1399.540(d)

The proposed deletions and additions to Section 1399.540(d) would allow a physician assistant to "refer the patient to a licensed healthcare provider competent to render the services needed for the task, procedure, or diagnosis" when the "task, procedure, or diagnostic problems exceeds [the physician assistant's] level of competence." Currently, physician assistants can only refer to physicians.

The changes to Section 1399.540(d) are concerning for a number of reasons. The regulations contemplate that the PA is making a referral because the level of care required exceeds the PA's level of competence; if a PA does not

have sufficient clinical training to treat the condition, the PA should be required to make the referral to a physician, who has substantially more training to properly determine the most appropriate referral pathway. This expanded referral authority creates the risk of causing patient harm due to the PA, who, despite having the best intentions, may make a referral that is inappropriate for the condition of a patient. An inappropriate referral increases the likelihood of unnecessary tests and procedures, higher health care costs, missed diagnoses, and worsening patient symptoms.

Furthermore, there is no proper statutory authority allowing PAs to refer to any other licensed healthcare provider other than a physician. The only place in SB 697 which contemplates referrals can be found in Business & Professions Code §3502.3(a)(1)(B), which states that a practice agreement may contain policies and procedures for "referrals between a physician and surgeon and the physician assistant." Nowhere in this statutory provision, or anywhere else in Chapter 7.7 of the Business & Professions Code which governs physician assistants, does it mention PAs making referrals to any other licensed healthcare provider other than a physician.

For the reasons stated above, CMA asks that the Board revert Section 1399.540(d) back to the existing language.

Surgical Procedures: Changes to 16 CCR §1399.541(i)(1)-(3)

The proposed changes to Section 1399.541 are alarming as they expand PA's scope in surgical procedures while at the same time lowering the supervisory standard for surgeries involving the deepest level of sedation, general anesthesia.

Addition of 'Procedural Sedation' category

The Board is proposing to expand Section 1399.541 by allowing physician assistants to perform surgical procedures without the personal presence of a physician not only for surgical procedures done with local anesthesia, but also for a new category of surgical procedures done under "procedural sedation."

Surgical procedures beyond those performed under local anesthesia would not be appropriate for a physician assistant to perform autonomously. Sedation is a continuum, beginning with minimal sedation such as local anesthesia, before progressing to moderate sedation, to deep sedation, and finally, to general anesthesia. Local anesthesia, as defined by the American Society of Anesthesiologists (ASA), is usually a one-time injection of medicine that numbs a small area of the body. It is used for procedures such as performing a skin biopsy or breast biopsy, repairing a broken bone, or stitching a deep cut.

The regulations do not define procedural sedation. This "procedural sedation" terminology is not uniformly used throughout medicine, making the regulation unclear. For example, the Centers for Medicare and Medicaid Services provides guidance on hospital anesthesia services that notes its expectation of how national guidelines are used in hospitals developing their policies on what medications, under what circumstances, constitute anesthesia. The guidance references national guidelines from the American Society of Anesthesiologists, the American College of Emergency Physicians (ACEP), the American Dental Association, and the American Society for Gastrointestinal Endoscopy and notes that "such organizations may not always fully agree with each other."

Ostensibly, the intention of the proposed regulations is to use the "procedural sedation" definition by ACEP, which says that it is a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures. Importantly, the ACEP policy clarifies that procedural sedation "encompasses a continuum of altered levels of consciousness (including minimal, moderate, deep, and dissociative sedation)." Procedural sedation is a critical intervention that requires training in airway interventions for support of patient ventilation and oxygenation, as well as support and monitoring of patient cardiovascular status. During procedures performed under 'procedural sedation,' patients may slip into a deeper level than anticipated, and the operator must prepare for this event. In situations where there is only one person operating, the lone operator must be prepared to abandon the procedure and rescue the patient.² Suffice to say, procedural sedation, as defined by the ACEP,3 is not simply an intermediate step on the sedation continuum as the proposed language suggests. PAs should not be allowed to perform surgical procedures under procedural sedation without the personal presence of a physician.

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

¹Thomas Benzoni and Marco Cascella, "Procedural Sedation," (Jan. 2023) National Library of Medicine: National Center for Biotechnology Information, available at https://www.ncbi.nlm.nih.gov/books/NBK551685/.

² Id

³ American College of Emergency Physicians, "Procedural Sedation in the Emergency Department," (Feb. 2023), available at https://www.acep.org/siteassets/new-pdfs/policy-statements/procedural-sedation-in-the-emergency-department.pdf

Both of these changes were incorporated, according to the Initial Statement of Reasons, to clarify the level of supervision required for physician assistants during surgical procedures, prompted by an event in which a patient's death occurred when the supervising physician was unavailable. CMA believes the proposed language would exacerbate that issue rather than addressing it by allowing PAs to perform surgical procedures under sedation levels at which the patient's ability to independently maintain ventilatory function may be impaired without the personal presence of a supervising physician. Physician assistants do not have the training required to rescue a patient from an unintended level of sedation and therefore put the patient at risk.

The change in supervisory standards for surgical procedures is objectionable because the resulting language removes what was previously a higher standard ("personal presence"), leaving behind only a singular, lower "immediately available" standard. "Immediately available" is a standard that already exists for situations wherein the PA is acting as a first or second assistant in surgery, as opposed to performing the surgical procedure themselves.

In its rationale, the Board further claims that Sections §1399.541(i)(1)-(3) was amended to tighten standards; the resulting language, however, has quite the opposite effect. The proposed definition of "immediately available" provides no substantial addition of clarity as compared to how it is currently defined in existing regulations. The Board did slightly alter the "immediately available" definition by removing the qualifier that the physician be available "upon the request of the physician assistant." However, the new definition does not explicitly require the physical presence of the supervising physician. For the Board to more effectively address the safety reasons purportedly motivating this change in supervisory standards, the Board could have instead considered keeping, and clearly defining, the "personal presence" standard rather than deleting it in favor of a singular "immediately available" standard.

While CMA is supportive of the intention of creating stricter supervision standards for general anesthesia procedures, the resulting language is ambiguous. Consequently, CMA believes that this amendment does not effectively enhance physician supervision requirements or safeguard the lives and well-being of California patients undergoing surgical procedures under general anesthesia.

The Board is exceeding the statutory authority of SB 697 by amending surgical procedure standards. We agree with the California Society of Anesthesiologists' concern that these expansions of PA scope in surgery

appear to be an attempt to insert provisions that were included in early versions of SB 697 that were eventually struck out from the final version of the bill due to patient safety concerns.

CMA asks that the Board revert to the existing regulations where the physician assistant shall only perform surgical procedures without the personal presence of the supervising physician that are customarily performed under local anesthesia.

Thank you for your consideration of our input and perspective. As mentioned, CMA supported the version of SB 697 eventually signed into law in 2019 and continues to be in favor of the resulting statutory law and its goal of creating a positive working relationship between physicians and physician assistant. However, the proposed SB 697 regulations as written stray from its statutory authority in ways that expand PA scope at the expense of patient safety.

We look 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 ctsui@cmadocs.org.

Sincerely,

Charlotte Tsui, Esq. Legal Counsel California Medical Association



Attachment 5

SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT

Senator Steven Glazer, Chair 2019 - 2020 Regular

Bill No: SB 697 Hearing Date: April 22, 2019

Author: Caballero Version: April 10, 2019

Urgency: No Fiscal: Yes

Consultant: Sarah Huchel

Subject: Physician assistants: practice agreement: supervision

SUMMARY: Revises the Physician Assistant Practice Act (Act) to allow multiple physicians and surgeons to supervise a physician assistant (PA), recasts the delegation of services agreement (DSA) as a practice agreement, eliminates the statutory requirement of medical records review, authorizes a physician and surgeon to supervise two additional PAs for a total of six, and makes other substantive and technical changes.

Existing law:

- 1) Establishes the Physician Assistant Board (PAB), comprised of five PAs and four public members. The duties of the PAB are as follows:
 - a) Establish standards and issue licenses of approval for programs for the education and training of PAs.
 - b) Make recommendations to the Medical Board of California (MBC) concerning the scope of practice for PAs.
 - c) Make recommendations to the MBC concerning the formulation of guidelines for the consideration of applications by licensed physicians to supervise PAs and approval of such applications.
 - d) Require the examination of applicants for licensure as a PA who meet the requirements of this chapter. (Business and Professions Code (BPC) Sections 3504, 3505, 3509)
- 2) Defines a DSA as the writing that delegates to a PA from a supervising physician the medical services the PA is authorized to perform. (BPC § 3501 (a)(10))
- 3) States that a PA acts as an agent of the supervising physician when performing any activity authorized by the Act. (BPC § 3501 (b))
- 4) Authorizes a PA to perform medical services under the supervision of a physician and surgeon who must be physically available to the PA. (BPC § 3502 (a)(2))

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

- 6) Authorizes a supervising physician and surgeon to delegate the authority to issue a drug order to a PA, and may limit this authority by specifying the manner in which the PA may issue delegated prescriptions by adopting a formulary and protocols that specify all criteria for the use of a particular drug or device. The drugs listed in the protocols shall constitute the formulary and shall include only drugs that are appropriate for use in the type of practice engaged in by the supervising physician and surgeon. When issuing a drug order, the PA is acting on behalf of and as an agent for a supervising physician and surgeon. (BPC § 3502.1 (a))
- 7) Limits a physician and surgeon to supervising up to four PAs at one time. (BPC § 3516 (b))
- 8) Limits a physician and surgeon to supervising no more than four nurse practitioners (NPs). (BPC § 2836.1)
- Authorizes a NP to furnish or order drugs or devices when operating in accordance with standardized protocols developed by the NP and supervising physician. (BPC § 2836.1)
- 10) States that physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include collaboration on the development of the standardized procedure, approval of the standardized procedure, and availability by telephonic contact at the time of patient examination by the NP. (BPC § 2831(d))
- 11) Authorizes a physician and surgeon to determine the extent of supervision necessary for an NP to furnish and order drugs. (BPC § 2831 (g)(2))

This bill:

- 1) Revises the Act's Legislative intent to strike references to PA's delegated authority and instead emphasizes coordinated care between healthcare professionals.
- 2) Updates the definition of "supervising physician" or "supervising physician and surgeon" by replacing reference to "improper use" of a PA with "prohibiting employment or supervision" of a PA.
- 3) Prohibits "supervision" from requiring the physical presence of the physician and surgeon.
- 4) Defines an "organized health care system" to include a licensed clinic, an outpatient setting, a health facility, a county medical facility, an accountable care organization, a home health agency, a physician's officer, a professional medical corporation, a medical partnership, a medical foundation, and any other organized entity that lawfully provides medical services, as specified.

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

- 6) Deletes the definition of and references to a "medical records review meeting."
- 7) Strikes references to the requirement that each medical record, for each episode of patient care, identifies the physician and surgeon responsible for the supervision of the PA.
- 8) Deletes the provision of law stating that a PA acts as an agent of the supervising physician when performing any activity under the Act.
- 9) Authorizes a PA to perform those medical services as set forth in regulations if the PA meets the following requirements:
 - a) The PA renders the services under the supervision of a licensed physician and surgeon who is not subject to a disciplinary condition imposed by the MBC or by the Osteopathic Medical Board prohibiting that supervision or prohibiting the employment of a PA.
 - b) The PA renders the services pursuant to a DSA or a practice agreement.
 - c) The PA is competent to perform the services.
 - d) The PA's education, training, and experience have prepared the PA to render the services.
- 10)Strikes references to a supervising physician and surgeon adopting protocols for some or all of the tasks performed by the PA, and the requirements for such protocols.
- 11) Prohibits the Act from being construed to require a physician to review or countersign a patient's medical record who was treated by a PA, unless required by the practice agreement. The PAB may, as a condition of probation of a licensee, require the review or countersignature of records of patients treated by a PA for a specified duration.
- 12) Redrafts provisions of law relating to PAs furnishing or ordering drugs and devices in context of the practice agreement.
- 13) Authorizes a PA to furnish or order a drug or device in accordance with the practice agreement and consistent with the PA's educational preparation or for which clinical competency has been established and maintained.

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14) Allows a physician and surgeon to supervise an additional two PAs at one time, for a total of six.

- 15) Requires a practice agreement to include the following:
 - a) The types of medical services a PA is authorized to perform and how the services are performed.
 - b) Policies and procedures to ensure adequate supervision of the PA, including but not limited to, appropriate communication, availability, consultations, and referrals between a physician and surgeon and the PA in the provision of medical services.
 - c) The methods for the continuing evaluation of the PA's competency and qualifications.
 - d) The furnishing or ordering of drugs or devices by a PA.
 - e) Any additional provisions agreed to by the PA and physician and surgeon or organized health care system.
- 16) Requires the practice agreement to be signed by both the PA and one or more physicians and surgeons or a physician and surgeon who is authorized to approve the practice agreement on behalf of the staff of the physicians and surgeons on the staff of an organized health care system.
- 17) Deems a DSA in effect prior to January 1, 2020 to meet the requirements of this bill.
- 18) Prohibits this bill from being construed to require the PAB's approval of a practice agreement.
- 19) Deletes provisions of law that conflict with the principle of multiple physician and surgeon supervision of a PA.
- 20) Deletes outdated sections of code relating to the requirement that a supervising physician and surgeon apply to the PAB and pay a fee.
- 21) Makes technical changes,
- 22) States that the provisions of this bill are severable, and if any provision of this bill or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

FISCAL EFFECT: Unknown. This bill is keyed fiscal by the Legislative Counsel.

COMMENTS:

1. **Purpose.** This bill is sponsored by the <u>California Academy of PAs</u>. According to the Author's office, "There are several disparities between PAs and other medical professionals in the same arena when it comes to the relationship between PAs and

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physicians. In practice, this means PAs are subject to burdensome regulations such as chart review, co-signatures, DSA requirements, and outdated ratios for prescribing purposes. These regulations incur a burden upon the physician as well, who may not be incentivized to hire a PA if a less regulated Nurse Practitioner is available.

"It is very possible that this disincentive to hire PAs may be contributing to the lack of healthcare services across out state, but especially in rural areas. If regulations were lessened on PAs to better match a Nurse Practitioner's status, there would be little or no disparity and PAs could be better utilized by physicians in areas where health care services are lacking. This bill seeks to reduce the burdens on the physician – PA relationship, so practices can thrive and potentially expand."

Background on the PA profession. According to the PAB, the concept of a PA originated in a 1961 article in the *Journal of the American Medical Association* calling for "an advanced medical assistant with special training, intermediate between that of the technician and that of the doctor, who could not only handle any technical procedures but could also take some degree of medical responsibility."

The first Physician Assistant training program began in 1965 at Duke University with the admission of four ex-military corpsmen into a two-year program. California began regulating the profession in 1970 "to redress the growing shortage and geographic misdistribution of health care services in California." The PA practice act permitted the supervised delegation of certain medical services to PAs, thus freeing physicians to focus their skills on other procedures.

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

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

A PA performs many of the same diagnostic, preventative, and health maintenance services as a physician. These services include, but are not limited to, the following:

- Taking health histories
- Performing physical examinations
- Ordering X-rays and laboratory tests
- Ordering respiratory, occupational, or physical therapy treatments
- Performing routine diagnostic tests
- Establishing diagnoses
- Treating and managing patient health problems
- Administering immunizations and injections
- Instructing and counseling patients

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Providing continuing care to patients in the home, hospital, or extended care facility

- Providing referrals within the health care system
- Performing minor surgery
- Providing preventative health care services
- Acting as first or second assistants during surgery
- Responding to life-threatening emergencies
- 4. **PA v. Nurse Practitioner**. Both PAs and NPs are mid-level healthcare professionals with overlapping scopes of practice. Each have distinct training and philosophies: nurses follow a patient-centered model in which they focus on disease prevention and health education, while PAs follow a disease-centered model in which they focus on the biologic and pathologic components of health.

PAs and NPs provide many of the same healthcare services, and are often considered for the same jobs. Indeed, a 2010 article from the *American College of Physicians' Center for Practice Improvement and Innovation*, "Hiring a Physician Assistant or Nurse Practitioner" notes:

"A PA or NP can increase your practice's accessibility, productivity, and revenue while contributing to excellent quality and patient satisfaction.... NPs/PAs are trained to provide a wide range of clinical care which includes the ability to conduct patient evaluations (interviews and physical evaluations), diagnose conditions (including ordering laboratory tests and interpreting results), develop and implement therapeutic plans, and provide preventive health services and counseling. These health care professionals can also handle many types of office visits, do certain procedures, support hospital and nursing home rounds, take after hours call, and contribute to care coordination/population management initiatives for the entire practice....

"Once you have decided to hire an NP or PA (as opposed to a physician), the choice between an NP or a PA may be dictated by the availability of qualified applicants."

In California, a substantial differentiating factor between the two professions is the comparatively higher level of administrative duties related to supervision required by the PA's Practice Act.

For these reasons, the sponsors of this bill argue that NPs are being favored over PAs for similar work. This bill is intended to align the supervisory and practice environments between NPs and PAs to create a level hiring field.

5. **Related Legislation.** AB 890 (Wood) would authorize a nationally certified NP to provide specified medical services without physician supervision if the NP, among other things, works in a specified integrated or organized health setting, or the NP meets specified education requirements and completes a 3-year transition to practice program. (Status: This bill is pending in the Assembly Appropriations Committee.)

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6. Prior Related Legislation. AB 3 (Bass, Chapter 376, Statutes of 2007) deleted the prohibition on the authority of a PA to issue a drug order for specified classes of controlled substances, required a PA and his or her supervising physician and surgeon to establish written supervisory guidelines and protocols, increased to four the number of PAs a physician and surgeon may supervise, and specified that services provided by a PA are included as covered benefits under the Medi-Cal program.

- <u>SB 1236</u> (Price, Chapter 332, Statutes of 2012) renamed the Physician Assistant Committee as the PAB and made related changes.
- <u>SB 337</u> (Pavley, Chapter 536, Statutes of 2015) provided two additional mechanisms for a supervising physician and surgeon to ensure adequate supervision of a PA functioning under protocols.
- 7. **Arguments in Support.** The <u>California Academy of PAs</u> writes, "By enhancing the flexibility of healthcare teams at the practice level, responsiveness to local patients' needs will be significantly improved.

"It is not the intent of California PAs to expand their scope of practice nor to attempt to practice independently. Neither is there a desire to eliminate a medical practice's authority to supervise the PA. The goal of <u>SB 697</u> is to allow the PA to work more effectively within the four walls of the practice by removing redundant and outmoded administrative constraints."

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

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

- 8. **Author's Amendments**. The Author wishes to make the following <u>technical</u> amendments:
 - 1. On page 5, line 40, replace "officer" with "office"
 - 2. On page 6, line 28, delete "the regulations to"; on page 6, line 29, delete "be adopted under"
 - 3. On page 10, line 6, delete "delegation of"; line 7, delete "services agreement or"
 - 4. On page 10, line 26, delete "This section shall not be construed to" and add "Nothing in statute or regulations shall"

- 5. On page 12, line 33 after "to" add "all of"
- 6. On page 13, line 25, delete "and specified"
- 7. On page 13, line 29, delete "a"; on line 30 delete "patient-specific protocol" and insert "the practice agreement or a patient-specific order"
- 8. On page 14, line 1, delete "Except as provided in subdivision (c),"
- 9. On page 14, line 31, replace "the" with "a"
- 10. On page 14, line 35, after "prescriber" add "for purposes of this code and the Health and Safety Code."
- 11. On page 14, line 39, delete ", but is not limited to,"
- 12. On page 15, line 22, delete "For purposes of the act adding this subdivision,"
- 13. On page 15, line 30, delete "for inclusion in a practice"; line 33, delete "agreement"

The Author also wishes to delete the obligation of the PAB to make recommendations to the Medical Board of California regarding the application of physicians to supervise PAs because applications and fees have not been collected by PAB since 2005.

14. Amend BPC § 3509 to strike subdivision (c).

SUPPORT AND OPPOSITION:

Support:

California Academy of PAs (Sponsor)
America's Physician Groups
Association of California Healthcare Districts
California Association for Health Services at Home
California Medical Association
California Psychiatric Association

Opposition:

None on file as of April 17, 2019.

Attachment 6

SENATE RULES COMMITTEE

Office of Senate Floor Analyses

(916) 651-1520 Fax: (916) 327-4478

THIRD READING

Bill No: SB 697

Author: Caballero (D), et al.

Amended: 4/24/19

Vote: 21

SENATE BUS., PROF. & ECON. DEV. COMMITTEE: 8-0, 4/22/19 AYES: Glazer, Chang, Archuleta, Dodd, Galgiani, Hill, Leyva, Wilk NO VOTE RECORDED: Pan

SENATE APPROPRIATIONS COMMITTEE: 6-0, 5/16/19 AYES: Portantino, Bates, Bradford, Hill, Jones, Wieckowski

SUBJECT: Physician assistants: practice agreement: supervision

SOURCE: California Academy of PAs

DIGEST: This bill revises the Physician Assistant Practice Act (Act) to allow multiple physicians and surgeons to supervise a physician assistant (PA), recasts the delegation of services agreement (DSA) as a practice agreement, eliminates the statutory requirement of medical records review, authorizes a physician and surgeon to supervise two additional PAs for a total of six, and makes other substantive and technical changes.

ANALYSIS:

Existing law:

1) Establishes the Physician Assistant Board (PAB), comprised of five PAs and four public members to establish standards and issue licenses of approval for programs for the education and training of PAs. (Business and Professions Code (BPC) Sections 3504)

- 2) Defines a DSA as the writing that delegates to a PA from a supervising physician the medical services the PA is authorized to perform. (BPC § 3501 (a)(10))
- 3) States that a PA acts as an agent of the supervising physician when performing any activity authorized by the Act. (BPC § 3501 (b))
- 4) Authorizes a PA to perform medical services under the supervision of a physician and surgeon who must be physically available to the PA. (BPC § 3502 (a)(2))
- 5) Requires the PA and the PA's supervising physician and surgeon to establish written guidelines for adequate supervision and adhere to specific medical records review processes. (BPC § 3502 (c))
- 6) Limits a physician and surgeon to supervising up to four PAs at one time. (BPC § 3516 (b))
- 7) Limits a physician and surgeon to supervising no more than four nurse practitioners (NPs). (BPC § 2836.1)
- 8) Authorizes a NP to furnish or order drugs or devices when operating in accordance with standardized protocols developed by the NP and supervising physician. (BPC § 2836.1)
- 9) States that physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include collaboration on the development of the standardized procedure, approval of the standardized procedure, and availability by telephonic contact at the time of patient examination by the NP. (BPC § 2831(d))
- 10) Authorizes a physician and surgeon to determine the extent of supervision necessary for an NP to furnish and order drugs. (BPC § 2831 (g)(2))

This bill:

1) Revises the Act's Legislative intent to strike references to PA's delegated authority and instead emphasizes coordinated care between healthcare professionals.

- 2) Updates the definition of "supervising physician" or "supervising physician and surgeon" by replacing reference to "improper use" of a PA with "prohibiting employment or supervision" of a PA.
- 3) Prohibits "supervision" from requiring the physical presence of the physician and surgeon.
- 4) Defines an "organized health care system" to include a licensed clinic, an outpatient setting, a health facility, a county medical facility, an accountable care organization, a home health agency, a physician's officer, a professional medical corporation, a medical partnership, a medical foundation, and any other organized entity that lawfully provides medical services, as specified.
- 5) Strikes references to a DSA and replaces it with "practice agreement," which means the writing, developed through collaboration among one or more physicians and surgeons, one or more PAs, and, if applicable, administrators of an organized health care system, that outlines the medical services the PA is authorized to perform and that grants approval for physicians and surgeons to supervise one or more PAs. States that any reference to a DSA relating to PAs in any other law shall have the same meaning as a practice agreement.
- 6) Deletes the definition of and references to a "medical records review meeting."
- 7) Strikes references to the requirement that each medical record, for each episode of patient care, identifies the physician and surgeon responsible for the supervision of the PA.
- 8) Deletes the provision of law stating that a PA acts as an agent of the supervising physician when performing any activity under the Act.
- 9) Authorizes a PA to perform those medical services as set forth in code if the PA meets the following requirements:
 - a) The PA renders the services under the supervision of a licensed physician and surgeon who is not subject to a disciplinary condition imposed by the MBC or by the Osteopathic Medical Board prohibiting that supervision or prohibiting the employment of a PA.
 - b) The PA renders the services pursuant to a practice agreement.

- c) The PA is competent to perform the services.
- d) The PA's education, training, and experience have prepared the PA to render the services.
- 10) Strikes references to a supervising physician and surgeon adopting protocols for some or all of the tasks performed by the PA, and the requirements for such protocols.
- 11) Prohibits the Act or any regulations from being construed to require a physician and surgeon to review or countersign a patient's medical record who was treated by a PA, unless required by the practice agreement. The PAB may, as a condition of probation of a licensee, require the review or countersignature of records of patients treated by a PA for a specified duration.
- 12) Redrafts provisions of law relating to PAs furnishing or ordering drugs and devices in context of the practice agreement or a patient-specific order.
- 13) Authorizes a PA to furnish or order a drug or device in accordance with the practice agreement and consistent with the PA's educational preparation or for which clinical competency has been established and maintained.
- 14) Allows a physician and surgeon to supervise an additional two PAs at one time, for a total of six.
- 15) Requires a practice agreement to include the following:
 - a) The types of medical services a PA is authorized to perform and how the services are performed.
 - b) Policies and procedures to ensure adequate supervision of the PA, including but not limited to, appropriate communication, availability, consultations, and referrals between a physician and surgeon and the PA in the provision of medical services.
 - c) The methods for the continuing evaluation of the PA's competency and qualifications.
 - d) The furnishing or ordering of drugs or devices by a PA.

- e) Any additional provisions agreed to by the PA and physician and surgeon or organized health care system.
- 16) Requires the practice agreement to be signed by both the PA and one or more physicians and surgeons or a physician and surgeon who is authorized to approve the practice agreement on behalf of the staff of the physicians and surgeons on the staff of an organized health care system.
- 17) Deems a DSA in effect prior to January 1, 2020 to meet the requirements of this bill.
- 18) Prohibits this bill from being construed to require the PAB's approval of a practice agreement.
- 19) Deletes provisions of law that conflict with the principle of multiple physician and surgeon supervision of a PA.
- 20) Deletes outdated sections of code relating to the requirement that a supervising physician and surgeon apply to the PAB and pay a fee.
- 21) Makes technical changes.
- 22) States that the provisions of this bill are severable, and if any provision of this bill or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

Background

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

A PA performs many of the same diagnostic, preventative, and health maintenance services as a physician.

PA v. Nurse Practitioner. Both PAs and NPs are mid-level healthcare professionals with overlapping scopes of practice. Each have distinct training and philosophies: nurses follow a patient-centered model in which they focus on disease prevention and health education, while PAs follow a disease-centered model in which they focus on the biologic and pathologic components of health.

PAs and NPs provide many of the same healthcare services, and are often considered for the same jobs. In California, a substantial differentiating factor between the two professions is the comparatively higher level of administrative duties related to supervision required by the PA's Practice Act.

For these reasons, the sponsors of this bill argue that NPs are being favored over PAs for similar work. This bill is intended to align the supervisory and practice environments between NPs and PAs to create a level hiring field.

FISCAL EFFECT: Appropriation: No Fiscal Com.: Yes Local: Yes According to the Senate Appropriations Committee:

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

SUPPORT: (Verified 5/15/19)

California Academy of PAs (source)
America's Physician Groups
Association of California Healthcare Districts
California Association for Health Services at Home
California Medical Association
California Psychiatric Association

OPPOSITION: (Verified 5/15/19)

California Chapter of the American College of Emergency Physicians Physician Assistant Board **ARGUMENTS IN SUPPORT:** The California Academy of PAs writes, "By enhancing the flexibility of healthcare teams at the practice level, responsiveness to local patients' needs will be significantly improved.

"It is not the intent of California PAs to expand their scope of practice nor to attempt to practice independently. Neither is there a desire to eliminate a medical practice's authority to supervise the PA. The goal of SB 697 is to allow the PA to work more effectively within the four walls of the practice by removing redundant and outmoded administrative constraints."

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

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

ARGUMENTS IN OPPOSITION: The California Chapter of the American College of Emergency Physicians writes that they are concerned that the current bill does not require the identification of a supervising physician and surgeon and allows for unlimited supervision of non-prescribing PAs.

Prepared by: Sarah Huchel / B., P. & E.D. / 5/18/19 11:34:21

**** END ****

Attachment 7

Date of Hearing: July 9, 2019

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS Evan Low, Chair

SB 697 (Caballero) - As Amended July 1, 2019

SENATE VOTE: 37-0

SUBJECT: Physician assistants: practice agreement: supervision

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

EXISTING LAW:

- 1) Regulates and licenses PAs under the Physician Assistant Practice Act. (Business and Professions Code (BPC) §§ 3500-3546)
- 2) Establishes, until January 1, 20201, the Physician Assistant Board (PAB) to administer and enforce the PA Practice Act. (BPC § 3504)
- 3) Defines a DSA as the writing that delegates to a PA from a supervising physician the medical services the PA is authorized to perform. (BPC § 3501(a)(10))
- 4) Specifies that that a PA acts as an agent of the supervising physician when performing any activity authorized by the Act. (BPC § 3501(b))
- 5) Authorizes a PA to perform medical services under the supervision of a physician and surgeon who must be physically available to the PA. (BPC § 3502(a)(2))
- 6) Requires the PA and the PA's supervising physician and surgeon to establish written guidelines for adequate supervision and adhere to specific medical records review processes. (BPC § 3502(c))
- 7) Authorizes a supervising physician and surgeon to delegate the authority to issue a drug order to a PA, and may limit this authority by specifying the manner in which the PA may issue delegated prescriptions by adopting a formulary and protocols that specify all criteria for the use of a particular drug or device. The drugs listed in the protocols must constitute the formulary and shall include only drugs that are appropriate for use in the type of practice engaged in by the supervising physician and surgeon. When issuing a drug order, the PA is acting on behalf of and as an agent for a supervising physician and surgeon. (BPC § 3502.1(a))

- 8) Authorizes a nurse practitioner to furnish or order drugs or devices when operating in accordance with standardized protocols developed by the nurse practitioner and supervising physician. (BPC § 2836.1)
- 9) Specifies that "supervision", as it relates to nurse practitioners and certified nurse-midwives, shall not be construed to require the physical presence of the physician, but does include collaboration on the development of the standardized procedure, approval of the standardized procedure, and availability by telephonic contact at the time of patient examination by the NP. (BPC §§ 2746.5, 2746.51, 2831(d))

THIS BILL:

- 1) Provides that "supervision" is not meant to require the physical presence of the physician and surgeon.
- 2) Defines "regulations" as the rules and regulations as set forth by the PAB, as those provisions read on June 7, 2019.
- 3) (8) (h) "Rou
- 4) Defines an "organized health care system" to include a licensed clinic, an outpatient setting, a health facility, a county medical facility, an accountable care organization, a home health agency, a physician's officer, a professional medical corporation, a medical partnership, a medical foundation, and any other organized entity that lawfully provides medical services, as specified.
- 5) Strikes references to a DSA and replaces it with "practice agreement," which means the writing, developed through collaboration among one or more physicians and surgeons, one or more PAs, and, if applicable, administrators of an organized health care system, that outlines the medical services the PA is authorized to perform and that grants approval for physicians and surgeons to supervise one or more PAs. States that any reference to a DSA relating to PAs in any other law shall have the same meaning as a practice agreement.
- 6) Deletes the definition of and references to a "medical records review meeting."
- 7) Strikes references to the requirement that each medical record, for each episode of patient care, identifies the physician and surgeon responsible for the supervision of the PA.
- 8) Deletes the provision of law stating that a PA acts as an agent of the supervising physician when performing activities authorized under the PA Practice Act.
- 9) Authorizes a PA to perform medical services under the PA Practice act if the PA meets the following requirements:
 - a) The PA renders the services under the supervision of a licensed physician and surgeon who is not subject to a disciplinary condition imposed by the MBC or by the Osteopathic Medical Board prohibiting that supervision or prohibiting the employment of a PA.
 - b) The PA renders the services pursuant to a practice agreement.

- c) The PA is competent to perform the services.
- d) The PA's education, training, and experience have prepared the PA to render the services.
- 10) Strikes references to a supervising physician and surgeon adopting written guidelines for some or all of the tasks performed by the PA.
- 11) Specifies that the PA Practice Act may not be construed to require a physician to review or countersign a patient's medical record who was treated by a PA, unless required by the practice agreement. The PAB may, as a condition of probation of a licensee, require the review or countersignature of records of patients treated by a PA for a specified duration.
- 12) Redrafts provisions of law relating to PAs furnishing or ordering drugs and devices in context of the practice agreement.
- 13) Authorizes a PA to furnish or order a drug or device in accordance with the practice agreement and consistent with the PA's educational preparation or for which clinical competency has been established and maintained.
- 14) Requires a practice agreement to include the following:
 - a) The types of medical services a PA is authorized to perform and how the services are performed.
 - b) Policies and procedures to ensure adequate supervision of the PA, including but not limited to, appropriate communication, availability, consultations, and referrals between a physician and surgeon and the PA in the provision of medical services.
 - c) The methods for the continuing evaluation of the PA's competency and qualifications.
 - d) The furnishing or ordering of drugs or devices by a PA.
 - e) Any additional provisions agreed to by the PA and physician and surgeon or organized health care system.
- 15) Requires the practice agreement to be signed by both the PA and one or more physicians and surgeons or a physician and surgeon who is authorized to approve the practice agreement on behalf of the staff of the physicians and surgeons on the staff of an organized health care system.
- 16) Deems a DSA in effect prior to January 1, 2020 to meet the requirements of this bill.
- 17) Specifies that the requirements under this bill may not be construed to require the PAB's approval of a practice agreement.
- 18) Deletes provisions of law that conflict with the principle of multiple physician and surgeon supervision of a PA.

- 19) Deletes outdated sections of code relating to the requirement that a supervising physician and surgeon apply to the PAB and pay a fee.
- 20) Makes technical and conforming changes.

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

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

COMMENTS:

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

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

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

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

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

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

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

In making the determination as to what a PA is allowed to perform, the physician also establishes case review and other requirements to ensure proper oversight. While there are statutory requirements as to the number of case reviews and other protections that a physician must meet, the physician's license is subject to discipline for any patient harm resulting from a PA's practice if the physician does not perform the appropriate oversight.

However, modern medical practice comes in many forms. According to the sponsors, the statutory limitations on case reviews and the single physician supervision model is overly burdensome and duplicative of other protections built in to the healthcare system, such as credentialing and privileging in organized health systems.

To reduce those duplicative requirements, this bill eliminates the statutory requirements for administrative oversight by physicians and instead requires physicians and PAs to determine for themselves the appropriate level of supervision, with every licensee involved in a specific practice agreement subject to discipline for improper supervision. Rather than require a statutory number of case reviews or meetings, this bill would require the physicians and PAs to outline the necessary details for the Medical Board of California and the PAB to determine whether patient harm was the result of individual incompetence or an improperly developed practice agreement.

ARGUMENTS IN SUPPORT:

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

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

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

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

The California Medical Association (CMA) writes, "CMA is dedicated to improving access and affordability to health care. One way to achieve this goal is to ensure physicians can assemble a full team of qualified health professionals to care for patients. Current administrative hurdles diminish incentives to working with physician assistants, and often result in physicians supervising less physician assistants than the law would allow. This means that the physician and their team are not at the full capacity of patients they could serve."

"[This bill] addresses these administrative hurdles specifically through removing fees for supervising physician assistants, easing restrictions in the current delegated services agreement between physicians and physician assistants, and transitioning this agreement into a Practice Agreement which will allow for the agreement to serve the relationship of a physician assistant and physicians in a practice, instead of to an individual physician. [This bill] also removes confusing chart review requirements, leaving in any necessary chart review to be determined by the supervising physicians. Finally, [This bill] allows for more autonomy to each medical practice as to their functional relationship with their physician assistants. We believe these administrative fixes will help to alleviate the burdens of working with physician assistants and increase the capacity of physicians and physician assistants to address critical access to care."

ARGUMENTS IN OPPOSITION:

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

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

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

- 1) The removal of the references to "organized health care system" because the board believes it allows for the corporate practice of medicine;
- 2) An amendment to the definition of "supervision" to allow for the physical presence of a physician, arguing that the language "shall not be construed" prevents the board and the Medical Board of California from disciplining a licensee when patient harm resulted from a practice agreement that did not require physical presence;
- 3) The striking of the language limiting regulations to those in effect June 7, 2019, as well as reauthorizing the board to establish regulations that limit the services a PA may perform;
- 4) The addition of language limiting the services a physician may delegate "to those tasks and procedures consistent with the supervising physician's specialty or usual and customary practice and with the patient's health condition;
- 5) And restoration of the current language regarding drug ordering and prescribing, rather than references to furnishing and ordering.

IMPLEMENTATION ISSUES:

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

AMENDMENTS:

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

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

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

- physician assistant. Supervision, as defined in this subdivision, shall not be construed to require the physical presence of the physician and surgeon. surgeon, but does require the following:
- (A) Adherence to adequate supervision as agreed to in the practice agreement.
- (B) The physician and surgeon be available by telephone or other electronic communication method at the time the PA examines the patient.
- (2) Nothing in this subdivision shall be construed as prohibiting the board from requiring the physical presence of a physician and surgeon as a term or condition of a PA's reinstatement or probation.
- 2) Regulations. The bill defines "regulations" throughout the PA Practice Act as the regulations read on June 7, 2019. According to the author and sponsors, this was a drafting error meant only to apply to the provisions relating to the pharmacology requirements. Therefore, the Committee may wish to amend the bill to delete the reference:
 - Page 4, lines 37-38, strike "Regulations, as those provisions read on June 7, 2019" and insert "Regulations.":
 - (g) "Regulations" means the rules and regulations as set forth in Division 13.8 (commencing with Section 1399.500) of Title 16 of the California Code of Regulations, as those provisions read on June 7, 2019. Regulations.
- 3) Organized Health Care Systems. This bill authorizes organized health care systems to collaborate with physicians and surgeons in developing practice agreements. Because organized health care systems are not necessarily medical or other professional corporations allowed to practice medicine, the Committee may wish to amend the bill to clarify that organized health care systems must comply with corporate practice requirements under the Medical Practice Act:
 - On page 5, line 10, strike "services." and insert: and is in compliance with Article 18 (commencing with Section 2400), of Chapter 5.":
 - (j) "Organized health care system" includes a licensed clinic as described in Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code, an outpatient setting as described in Chapter 1.3 (commencing with Section 1248) of Division 2 of the Health and Safety Code, a health facility as described in Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, a county medical facility as described in Chapter 2.5 (commencing with Section 1440) of Division 2 of the Health and Safety Code, an accountable care organization, a home health agency, a physician's office, a professional medical corporation, a medical partnership, a medical foundation, and any other entity that lawfully provides medical services. services and is in compliance with Article 18 (commencing with Section 2400), of Chapter 5.

REGISTERED SUPPORT:

California Academy of PAs (sponsor)

America's Physician Groups

Association of California Healthcare Districts, and Affiliated Entity Alpha Fund

California Academy of Family Physicians

California Association for Health Services At Home

California Hospital Association California Medical Association California Psychiatric Association Californiahealth+ Advocates

Medical Board of California

REGISTERED OPPOSITION:

California Chapter of the American College of Emergency Physicians (unless amended)

California Rheumatology Alliance (unless amended)

California Society of Plastic Surgeons

Physician Assistant Board (unless amended)

1 individual (unless amended)

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

Attachment 8

SENATE RULES COMMITTEE

Office of Senate Floor Analyses

(916) 651-1520 Fax: (916) 327-4478

UNFINISHED BUSINESS

Bill No: SB 697

Author: Caballero (D), et al.

Amended: 9/3/19 Vote: 21

SENATE BUS., PROF. & ECON. DEV. COMMITTEE: 8-0, 4/22/19 AYES: Glazer, Chang, Archuleta, Dodd, Galgiani, Hill, Leyva, Wilk NO VOTE RECORDED: Pan

SENATE APPROPRIATIONS COMMITTEE: 6-0, 5/16/19 AYES: Portantino, Bates, Bradford, Hill, Jones, Wieckowski

SENATE FLOOR: 37-0, 5/23/19

AYES: Allen, Archuleta, Atkins, Bates, Beall, Borgeas, Bradford, Caballero, Chang, Dodd, Durazo, Galgiani, Glazer, Grove, Hertzberg, Hill, Hueso, Hurtado, Jackson, Jones, Leyva, McGuire, Mitchell, Monning, Moorlach, Morrell, Nielsen, Portantino, Roth, Rubio, Skinner, Stern, Stone, Umberg,

Wieckowski, Wiener, Wilk NO VOTE RECORDED: Pan

ASSEMBLY FLOOR: 79-0, 9/9/19 - See last page for vote

SUBJECT: Physician assistants: practice agreement: supervision

SOURCE: California Academy of PAs

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

Assembly Amendments retain the ratio under current law of one to four for physician supervision of PAs; clarify that PAs can furnish or order a drug or device in accordance with the practice agreement, consistent with the PA's education and clinical training, and for Schedule II or III controlled substances, in accordance with the practice agreement or a patient-specific order approved by the treating or supervising physician and surgeon and; make various conforming and technical changes.

ANALYSIS:

Existing law:

- 1) Establishes the Physician Assistant Board (PAB), comprised of five PAs and four public members to establish standards and issue licenses of approval for programs for the education and training of PAs. (Business and Professions Code (BPC) Sections 3504)
- 2) Defines a DSA as the writing that delegates to a PA from a supervising physician the medical services the PA is authorized to perform. (BPC § 3501 (a)(10))
- 3) Authorizes a PA to perform medical services under the supervision of a physician and surgeon who must be physically available to the PA. (BPC § 3502 (a)(2))
- 4) Requires the PA and the PA's supervising physician and surgeon to establish written guidelines for adequate supervision and adhere to specific medical records review processes. (BPC § 3502 (c))
- 5) Limits a physician and surgeon to supervising up to four PAs at one time. (BPC § 3516 (b))

This bill:

1) Strikes references to a DSA and replaces it with "practice agreement," which means the writing, developed through collaboration among one or more physicians and surgeons and one or more PAs that outlines the medical services the PA is authorized to perform and that grants approval for physicians and surgeons to supervise one or more PAs.

- 2) Deletes various requirements related to supervision limitations, medical records reviews and meetings, and written guidelines, among other things.
- 3) Redrafts provisions of law relating to PA requirements, furnishing or ordering of drugs and devices, and the PAB's disciplinary authority in the context of the practice agreement.
- 4) Specifies requirements that must be outlined in a practice agreement including, supervision, competency, and other aspects of the PA and physician relationship.
- 5) Deems a DSA in effect prior to January 1, 2020 to meet the requirements of this bill.

Background

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

A PA is authorized to perform many of the same diagnostic, preventative, and health maintenance services as a physician. Under current law, these services are authorized under a contractual and statutory agreement called a delegation of services agreement (DSA). The DSA outlines everything the PA is allowed to do. In establishing a DSA, a supervising physician uses professional and clinical judgment to review the PAs competency to perform a variety of services. There are statutory requirements as to the number of case reviews and other protections that must be included in a DSA, and the supervising physician's license is subject to discipline for any patient harm resulting from a PA's practice if the physician does not perform the appropriate oversight.

However, according to the bill's sponsors, statutory limitations on case reviews and the single physician supervision model is overly burdensome and duplicative of other protections built in to the healthcare system, such as credentialing and privileging in organized health systems. To reduce those duplicative requirements, this bill eliminates the statutory requirements for administrative oversight by physicians and instead requires physicians and PAs to determine for themselves the appropriate level of supervision, with every licensee involved in a specific practice agreement subject to discipline for improper supervision.

FISCAL EFFECT: Appropriation: No Fiscal Com.: Yes Local: Yes

According to the Assembly Committee on Appropriations, this bill will result in minor and absorbable costs to the PAB.

SUPPORT: (Verified 9/9/19)

California Academy of PAs (source)

America's Physician Groups

Association of California Healthcare Districts, and Affiliated Entity Alpha Fund

California Academy of Family Physicians

California Association for Health Services At Home

California Hospital Association

California Medical Association

California Orthopedic Association

Californiahealth+ Advocates

Medical Board of California

Physician Assistant Board

OPPOSITION: (Verified 9/9/19)

California Chapter of the American College of Emergency Physicians

California Rheumatology Alliance

California Society of Plastic Surgeons

ARGUMENTS IN SUPPORT: Supporters note that PAs increase the reach of a medical practice. They are well-received by patients for their skill and care. PAs are the plentiful, youthful, and vital component of the California healthcare workforce for today and the future. Supporters state that by creating greater flexibility for the care team, this bill lays the ground work to guarantee that California continues to have the healthcare workforce it needs. Health centers, and other care settings, will be able to better utilize their full care team and make decisions that are right for their local needs.

According to the California Medical Association, "SB 697 allows for more autonomy to each medical practice as to their functional relationship with their physician assistants. We believe these administrative fixes will help to alleviate the burdens of working with physician assistants and increase the capacity of physicians and physician assistancts to address critical access to care."

ARGUMENTS IN OPPOSITION: The California Chapter of the American College of Emergency Physicians is opposed unless amended to a previous version of this bill. While many of the concerns were addressed in the latest set of amendments, they still note that "[this bill] would allow a PA in the ED to be supervised by a cardiologist who may have privileges in the emergency department to provide on-call cardiology services but is not privileged to provide the services of an emergency physician which are necessary to supervise the PA."

The California Society of Plastic Surgeons and the California Rheumatology Alliance were opposed unless amended to a previous version of this bill. While many of their concerns have been addressed in various amendments to this bill, they had asked for an additional amendment to the bill requiring physician review of PA medical records.

ASSEMBLY FLOOR: 79-0, 9/9/19

AYES: Aguiar-Curry, Arambula, Bauer-Kahan, Berman, Bigelow, Bloom, Boerner Horvath, Bonta, Brough, Burke, Calderon, Carrillo, Cervantes, Chau, Chen, Chiu, Choi, Chu, Cooley, Cooper, Cunningham, Daly, Diep, Eggman, Flora, Fong, Frazier, Friedman, Gabriel, Gallagher, Cristina Garcia, Eduardo Garcia, Gipson, Gloria, Gonzalez, Gray, Grayson, Holden, Irwin, Jones-Sawyer, Kalra, Kamlager-Dove, Kiley, Lackey, Levine, Limón, Low, Maienschein, Mathis, Mayes, McCarty, Medina, Melendez, Mullin, Muratsuchi, Nazarian, Obernolte, O'Donnell, Patterson, Petrie-Norris, Quirk, Quirk-Silva, Ramos, Reyes, Luz Rivas, Robert Rivas, Rodriguez, Blanca Rubio, Salas, Santiago, Smith, Mark Stone, Ting, Voepel, Waldron, Weber, Wicks, Wood, Rendon

Prepared by: Sarah Mason / B., P. & E.D. /

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