MEMORANDUM

DATE	January 28, 2021
TO	Physician Assistant Board (Board)
FROM	Rozana Khan, Executive Officer Karen Halbo, Regulations Counsel, Attorney III
SUBJECT	Agenda Item 10a. Amending 16 CCR Sections 1399.502, 1399.505, 1399.506, 1399.507, 1399.511, 1399.530, 1399.540, 1399.541, 1399.545, 1399.546 to Implement SB 697

Background

Senate Bill 697 (SB) (Caballero, Chapter 707, Statutes of 2019) made changes to Physician Assistant (PA) practice. At the August 7, 2020 WebEx on-line Board meeting, the Board discussed and voted to make amendments to 16 CCR Sections 1399.502, 1399.505, 1399.506, 1399.507, 1399.511, 1399.530, 1399.540, 1399.541, 1399.545, and 1399.546 (the SB 697 impacted regulations). It was subsequently brought to staff's attention that meeting materials inadvertently had not been made available to interested parties before the August 7, 2020 Board meeting.

At the November 9, 2020 Board meeting it was brought to the Board's attention that 16 CCR 1399.530, 1399.610, and 1399.612 were all "locked" or "tombstoned" by the changes that SB 697 made to Business and Professions Code (BPC) section 3502.1. In section 3502.1 of the BPC, references are made to those three Board regulations "as those provisions read on June 7, 2019," which hamstrings the Board from being able to revise 16 CCR 1399.530, 1399.610, and 1399.612 when revisions are needed. At the meeting, the California Academy of PAs (CAPA) raised the issue of not having access to the meeting materials for the August 7, 2020 Board meeting before that meeting and for some time after that meeting. The Board did not take action on the SB 697 impacted regulations at the meeting.

On November 12, 2020, CAPA wrote to both the President of the CA Medical Board and the President of PA Board, asking for an opportunity for meaningful public input into the Board's rulemaking to implement SB 697, and explaining their concerns. On January 14, 2021, Board President Juan Armenta, former Board President Jed Grant, Executive Officer Rozana Khan, Analyst Julie Caldwell, Board counsel Will Maguire, and regulations counsel Karen Halbo met with representatives from CAPA to discuss CAPA's concerns about the proposed language the Board voted on at the August 7, 2020 meeting. Staff has provided the Board with the language already adopted by the board and indicates suggested changes described in this memo with a double strikethrough to show deletions and double-underline to show additions to the already-adopted proposed language.

16 CCR 1399.502, 1399.505, 1399.507, 1399.511, 1399.545, and 1399.546

CAPA did not have concerns with the proposed language for 16 CCR Sections 1399.502, 1399.505, 1399.507, 1399.511, and 1399.546 at the January 14, 2021 meeting. In preparing the revised text, staff suggested revisions to two sections. In 16 CCR 1399.511, subdivision (a), the phrase "or approval" should be removed (the Board no longer grants approval to PA training programs), and in the Note, the Reference section mistakenly cites section 2021 of the BPC, which should be corrected to section 3522 of the BPC. In 16 CCR 1399.545, subdivision (a), the term "should" should be replaced by the term "shall" for clarity. CAPA did not discuss their concerns with 16 CCR Section 1399.545 at the meeting but did mention some concerns with this section in footnote 17 of their November 12, 2020 letter.

16 CCR 1399.506

CAPA raised concerns about the language in 16 CCR 1399.506, subdivisions (e)&(f). Subdivision (e) requires an applicant to disclose whether they have any malpractice history and submit a written statement of any incident. "Any malpractice history" is broader than a requirement to disclose malpractice claims that had settled or had gone to judgment, and includes malpractice claims involving very small payment, or even no payment. The Board already obtains some malpractice information on applicants by doing a check with the National Practitioner Databank (NPDB), which reports if an applicant has had a malpractice judgment or settlement in an amount greater than $30,000. CAPA also pointed out that subdivision (f) was overbroad and staff agreed. In response to the comments, the proposed revised language limits disciplinary history that an applicant must report to only formal discipline and only formal discipline received during their physician assistant training program.

16 CCR 1399.530

This section is locked, or tombstoned, by BPC section 3502,1(e)(1) and must be removed from the proposed text.

16 CCR 1399.540

CAPA raised concerns about the language in 16 CCR 1399.540, subdivisions (a) and (b), as both subdivisions contain references to the outdated phrase "delegation of services" which SB 697 replaced with "the practice agreement" as set out in section 3502 of the BPC. Staff agreed with these concerns and has struck out the old language and replaced both subdivisions (a) and (b) with revised language that cites to the BPC.

16 CCR 1399.541

On former president Grant's request, in the first paragraph of this regulation, the phrase, "and a physician assistant acts as an agent for that physician and surgeon," has been struck because while agency is an option in the practice agreement, it is no longer universal.

CAPA raised significant concerns about 16 CCR 1399.541 subdivision (i) paragraph (1) - regarding requiring supervision during surgical procedures; and subdivision (j) - regarding the language provided related to obtaining informed consent. CAPA cited to

BPC section 3501, subdivision (f), paragraph (1), sub-paragraphs (A) & (B), saying that the Board lacks the authority to specify supervision requirements on a PA performing surgical procedures, and quoted BPC section 3501, subdivision (f), paragraph (1), which says that PA supervision cannot require the physical presence of the supervising physician.
Board president Armenta and former board president Grant and staff believe the Board can only meet its consumer protection mandate by requiring the supervising physician be "immediately available" when a PA is performing surgical procedures on a patient under general anesthesia. The phrase "immediately available" is already defined in detail in the existing language of 16 CCR 1399.541, subdivision (i), paragraph (2). Requiring the supervising physician to remain immediately available makes it possible for the supervising physician to return and take over or advise and assist the PA if something goes wrong. This requirement simply defines what is "adequate supervision" under those circumstances. The supervising physician does not need to remain at the PA's side, or even in the operating room where the surgical procedures are taking place. The supervising physician is only required to remain nearby, where he or she can be reached and can return to the operating room should something go wrong.

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

CAPA raised the concern that the language in 16 CCR 1399.541, subdivision (j) was overly detailed and unnecessary for simply allowing a PA to obtain patient consent for recommended treatment, and board president Armenta and former board president Grant agreed. Subdivision (j) was edited to allow a PA to obtain consent for recommended treatments and requires that consent be documented in the patient's medical record. Without a California statute that defines or requires obtaining informed consent from a patient, it would be difficult to clearly define the term. (Informed consent as a legal doctrine arises out of case law - healthcare practitioners obtain informed consent from patients to avoid liability on the charge of assault).

16 CCR 1399.545

In response to CAPA's concerns and per former president Grant's instructions, in 16 CCR 1399.545, subdivision (e), the phrase at the end of the sentence "which shall include: one or more of the following:" was struck, as were the following paragraphs:

(1) - requiring monthly meetings during the first six months of a new practice agreement between a supervising physician and a PA,
(2) – requiring meetings once every six months for existing practice agreements between a supervising physician and a PA,
(3) – requiring a written record be kept of such meetings between a supervising physician and a PA,
(4) – requiring the supervising physician develop a quality assurance program to maintain the standard of care, and conduct an onsite inspection every quarter to monitor the quality of care provided by the PA.

Former president Grant also instructed that, in 16 CCR 1399.545, subdivision (f), the term "autonomously" be replaced with the term "independently."

16 CCR 1399.546

Former president Grant requested the addition to 16 CCR 1399.546, subdivision (a) of: "When providing care to patients in a general acute care hospital as defined in Section 1250 of the Health and Safety Code," and the following word "each" was un-capitalized to clarify this requirement (following BPC section 3502(c)&(f)). For clarity, the start of the last sentence of subdivision (a) has been revised to read, "When transmitting an oral order, the PA shall also…"

Action Requested

The Board is asked to make a motion to remove 16 CCR 1399.530 from this regulation package and to approve the revisions to the other text language as shown on the attached revised text, and direct the Executive Officer to take all steps necessary to initiate the rulemaking process, authorize the Executive Officer to make any technical or non-substantive changes to the rulemaking package, notice the revised text for a 45-day comment period and, if no adverse comments are received during the 45-day comment period and no hearing is requested, adopt the proposed regulatory changes.

Attachments:

1. Letter from the California Academy of PAs (CAPA), dated November 12, 2020
2. Revised text for SB 697 Implementation regulation package (Amending 16 CCR Sections 1399.502, 1399.505, 1399.506, 1399.507, 1399.511, 1399.540, 1399.541, 1399.545, and 1399.546)

November 12, 2020

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

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

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

Dear Presidents Pines, Grant and Honorable Board Members:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

REGULATION 1399.506. FILING OF APPLICATIONS

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

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

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

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

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

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

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

Moreover, section 3509 provides as follows:

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

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

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

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

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

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

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

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

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

REGULATION 1399.540 LIMITATION ON MEDICAL SERVICES

Subdivision (a) PAB Proposed Changes:

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

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

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

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

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

> The new law instead authorizes a physician assistant to perform medical services authorized by the Act if certain requirements are met, including that the medical services are rendered **pursuant to a practice agreement**, as defined and the physician assistant is competent to perform the medical services.

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

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

CAPA RESPECTFULLY SUGGESTS:

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

> ~~(a) A physician assistant may only provide those medical services which he or she is they are competent to perform and which are consistent with the physician assistant's education, training, and experience, and which are delegated in writing by a supervising physician who is responsible for the patients cared for by that physician assistant.~~
>
> **(**a) A PA may provide those medical services which they are authorized to perform and which are consistent with the PA's education, training, and experience, and which are rendered under the supervision of a licensed physician and surgeon pursuant to a practice agreement in accordance with Section 3502 of the Business and Professions Code.

Subdivision (b) PAB Proposed Changes:

> (b) The writing which delegates the medical services shall be known as a ~~delegation of services~~ practice agreement. A ~~delegation of services~~ practice agreement shall be signed and dated by the physician assistant and one or more physicians and surgeons or a physician and surgeon who is authorized to approve the practice agreement on behalf of the physicians and surgeons on the staff of an organized health care system~~. Each supervising physician. A delegation of services agreement may be signed by more than one supervising physician only if the same medical services have been delegated by each supervising physician. A physician assistant may provide medical services pursuant to agreement.~~

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

CAPA RESPECTULLY SUGGESTS (additions in bold):

> (b) The writing which ~~**delegates**~~ **defines** the medical services **the PA is authorized to perform** shall be known as a ~~delegation of services~~ practice agreement. A ~~delegation of services~~ practice agreement shall be signed and dated by the ~~**physician assistant**~~ **PA** and one or more physicians and surgeons or a physician and surgeon who is authorized to approve the practice agreement on behalf of the physicians and surgeons on the staff of an organized health care system~~. Each supervising physician. A delegation of services agreement may be signed by more than one supervising physician only if the same medical services have been~~

~~delegated by each supervising physician. A physician assistant may provide medical services pursuant to agreement.~~

1399.541. MEDICAL SERVICES PERFORMABLE[9]

PAB Proposed Changes:

> Because physician assistant practice is directed by a supervising physician, and a physician assistant acts as an agent for that physician and surgeon, the orders given and tasks performed by a physician assistant shall be considered the same as if they had been given and performed by the supervising physician. Unless otherwise specified in these regulations or in the ~~delegation~~ practice agreement or protocols, these orders may be initiated without the prior patient specific order of the supervising physician.
>
> In any setting, including for example, any licensed health facility, out-patient setting, patients' residence, residential facility, and hospice, as applicable, a physician assistant may, pursuant to a ~~delegation~~ practice agreement and where present, protocols:

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

Moreover, the use of the word "agent" also must be reformed. Section 3502.3 (a)(4) makes it clear that a practice agreement "may" designate a PA as an agent, but it need not do so. In unlawful contrast, the regulation deems a PA always to be an agent: "Because … a physician assistant acts as an agent…" This must be changed to reflect and be authorized under current law.

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

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

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

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

CAPA RESPECTFULLY SUGGESTS:

> ~~**Because physician assistant**~~ **PA** practice **is authorized in a practice agreement, under the supervision of a physician and surgeon, in accordance with Section 3502 of the Business and Professions Code. In instances where the practice agreement specifies that the PA acts as an agent for that physician and surgeon** ~~**is directed by a supervising physician, and a physician assistant acts as an agent for that physician and surgeon,**~~ the orders given and tasks performed by ~~a physician assistant~~ the PA shall be considered the same as if they had been given and performed by the supervising physician. Unless otherwise specified in these regulations or in the ~~delegation~~ practice agreement ~~**or protocols,**~~ these orders may be initiated without the prior patient specific order of the supervising physician.
>
> In any setting, including for example, any licensed health facility, out-patient setting, patients' residence, residential facility, and hospice, as applicable, a ~~physician assistant~~ **PA** may~~, pursuant to a delegation practice agreement~~ **perform any task, authorized by Section 3502 of the Business and Professions Code, including, but not limited to, the following:** ~~**and where present, protocols**~~**:**

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

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

> (i) (1) Perform surgical procedures without the personal presence of the supervising physician which are customarily performed under local anesthesia. Prior to delegating any such surgical procedures, the supervising physician shall review documentation which indicates that the physician assistant is trained to perform the surgical procedures. All other surgical procedures requiring other forms of anesthesia may be performed by a physician assistant only in the personal presence of a supervising physician.

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

Second, the regulation unlawfully and directly contradicts current law when it provides that a PA may perform procedures requiring anesthesia "only in the personal presence of a supervising physician." The only requirement in current law applicable to this situation is that a PA must be in some manner "supervised" by a physician and surgeon with the exact contours of that

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

CAPA RESPECTFULLY SUGGESTS:

> (i) (1) Perform surgical procedures **as authorized by the practice agreement; which the PA is competent to perform and consistent with the PA's education, training, and experience, and rendered under the supervision of a licensed physician and surgeon in accordance with Section 3502 of the Business and Professions Code**. ~~**without the personal presence of the supervising physician which are customarily performed under local anesthesia. Prior to delegating any such surgical procedures, the supervising physician shall review documentation which indicates that the physician assistant is trained to perform the surgical procedures. All other surgical procedures requiring other forms of anesthesia may be performed by a physician assistant only in the personal presence of a supervising physician.**~~

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

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

> (i)(2) A physician assistant may also act as first or second assistant in surgery under the supervision of a supervising physician. The physician assistant may so act without the personal presence of the supervising physician if the supervising physician is immediately available to the physician assistant. "Immediately available" means the physician and surgeon is physically accessible and able to return to the patient, without any delay, upon the request of the physician assistant to address any situation requiring the supervising physician's services.

DISCUSSION: Here, the regulation specifies with (excuse the pun) surgical precision exactly the kind of supervision that is required in surgical settings: "The physician assistant may so act without the personal presence of the supervising physician if the supervising physician *is immediately available* to the physician assistant. "Immediately available" means the physician and surgeon *is physically accessible and able to return to the patient*, without any delay, upon the request of the physician assistant to address any situation requiring the supervising physician's services."

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

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

Second, and more broadly, PAB micromanagement of the exact nature of and conditions for the supervisorial relationships between physicians and surgeons and PAs is, post SB 697, unlawful, and contradicted by statute. Except for those enumerated restrictions on PA practice set forth in section 3502 which cannot be waived or altered by practice agreements, *all other matters relating to the relationship between the physician and surgeon and the PA – including supervision -- are now exclusively a matter between the parties to a practice agreement.* Thus, while some routine surgical procedures, such as the removal of a wart, by an experienced PA may require one level of supervision as reflected in an agreement, other kind of surgical interventions such as open-heart surgery may require closer supervision as controlled by the practice agreement and the applicable standard of care based on the PA's education, training, and experience.

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

Section 3502, which establishes a PA's right to practice, with emphasis added, reads in part:

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

The statute begins, "[n]otwithstanding any other law." This means no other statute *or regulation* can contradict it.

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

> [T]this bill eliminates the statutory requirements for administrative oversight by physicians and instead requires physicians and PAs ***to determine for themselves the appropriate level of supervision***, with every licensee involved in a specific practice agreement subject to discipline for improper supervision.

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

CAPA RESPECTFULLY SUGGESTS:

> (i)(2) A physician assistant may also act as first or second assistant in surgery **as authorized by the practice agreement; which the PA is competent to perform and consistent with the PA's education, training, and experience, and rendered under the supervision of a licensed physician and surgeon in accordance with Section 3502 of the Business and Professions Code**. ~~**under the supervision of a supervising physician. The physician assistant may so act without the personal presence of the supervising physician if the supervising physician is immediately available to the physician assistant. "Immediately available" means the physician and surgeon is physically accessible and able to return to the patient, without any delay, upon the request of the physician assistant to address any situation requiring the supervising physician's services.**~~

Subdivision (j) PAB Proposed Changes:

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

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

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

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

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

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

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

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

Second, the proposal violates section 3502 for the reasons explained above. How physicians and surgeons interpret the legal requirements of informed consent and operationalize those requirements is a matter reposed to their professional judgements as memorialized in the practice agreement.

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

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

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

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

CAPA RESPECTFULLY SUGGESTS:

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

CONCLUSION

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

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

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

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

Very truly yours,

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

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

Implementation of SB 697 regulation package

Using the Text language adopted by the Board, additions are shown by double underline, and deletions are indicated by ~~double strikethrough~~.

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" or "PA" means a person who is licensed by the ~~b~~Board as a physician assistant.

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

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

(f) "Supervising physician" ~~and "physician supervisor"~~ or "supervising physician and surgeon" means a physician and surgeon licensed by the Medical Board of California or~~a physician licensed~~ by the Osteopathic Medical Board of California and who supervises one or more physician assistants, who possesses a current valid license to practice medicine, and who is not currently on disciplinary probation prohibiting the employment or supervision of a physician assistant.

(g) (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, but does require:

(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 imposition of discipline.

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

(i) "Practice agreement" means the writing, developed through collaboration among one or more physicians and surgeons and one or more physician assistants, that defines the medical services the physician assistant is authorized to perform pursuant to Section 3502 and that grants approval for physicians and surgeons on the staff of an organized health care system to supervise one or more physician assistants in the organized health care system. Any reference to a delegation of services agreement relating to

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physician assistants in any other law shall have the same meaning as a practice agreement.

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

Implementation of SB 697 regulation package

Using the Text language adopted by the Board, additions are shown by double underline, and deletions are indicated by ~~double strikethrough~~.

1399.506. ~~Filing of~~ Applications~~s~~ for Licensure.

(a) ~~Applications for~~ As a condition of initial licensure as a physician assistant ~~shall be filed on a form provided by the board~~ an applicant must submit all required fees, two (2) classifiable sets of fingerprint cards or a Live Scan inquiry to establish the identity of the applicant and to permit the Board to conduct a criminal history record check, and a completed application for licensure to the Board at its Sacramento office ~~and accompanied by the fee required in section 1399.550~~ that contains all of the following:

(1) personal information including:

(A) the legal name of the applicant and any associated aliases.

(B) the gender of the applicant.

(C) the applicant's social security number or identifying tax information number.

(D) the applicant's address of record or mailing address.

(E) the applicant's date of birth.

(F) the applicant's telephone numbers for home and cell.

(G) the applicant's email address.

(2) all disclosures required by this section, and

(3) a declaration under penalty of perjury, signed and dated by the applicant, that the information submitted on the application is true and correct.

For the purposes of this subdivision "required fees" includes the license application processing fee and the initial license fee as set forth in section 1399.550. The applicant shall pay any costs for furnishing fingerprints and conducting the criminal history record check.

(b) While disclosure of military service is voluntary, an applicant who has served as an active duty member of the Armed Forces of the United States, was honorably discharged, and who provides evidence of such honorable discharge shall have their application review expedited pursuant to section 115.4 of the Code. ~~Applications for approval of programs for the education and training of physician assistants shall be filed on a form provided by the board at its Sacramento office and accompanied by the fee required in section 1399.556.~~

(c) If the applicant is married to, or in a domestic partnership or other legal union with, an active-duty member of the armed forces of the United States who is assigned to a duty station in California under official active-duty military orders, or if the applicant holds a current physician assistant license in another state, and provides evidence of either condition, their application review will be expedited pursuant to section 115.6 of the Code.

(d) As a condition of licensure, an applicant shall disclose whether they have any other licenses, registrations, or certificates in any healthcare occupation and list the

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status, number, and issuing state of those licenses, registrations, or certificates.

(e) As a condition of licensure, an applicant shall disclose whether they have any malpractice history and submit a written statement of any incident. *(Board to discuss)*

(f) As a condition of licensure, an applicant shall disclose whether they have any formal disciplinary history from their ~~school~~ physician assistant training program or against any other licenses, registrations, or certifications issued by any state and submit a written statement of any incident.

NOTE: Authority cited: Sections 2018 and 3510, Business and Professions Code. Reference: Sections 3509 and 3513, Business and Professions Code.

Using the Text language adopted by the Board, additions are shown by double underline, and deletions are indicated by ~~double strikethrough~~.

1399.507 Examination Required.

The written examination for licensure as a physician assistant is that administered by the National Commission on Certification of Physician Assistants. Successful completion requires that the applicant has~~ve~~ achieved the passing score ~~established by the board~~ for that examination. It is the responsibility of the applicant to ensure that certification of ~~his or her~~ their examination score is received by the Board.

NOTE: Authority cited: Section 3510, Business and Professions Code. Reference: Sections 851, ~~3515,~~ and 3517, Business and Professions Code.

Implementation of SB 697 regulation package

Using the Text language adopted by the Board, additions are shown by double underline, and deletions are indicated by ~~double strikethrough~~.

1399.511. ~~Notice of Change of~~ Address of Record.

(a) Each person submitting an application for licensure to the Board must include a valid mailing address which will be released by the Board to the public and posted on the Board's website. The mailing address is used for services of all official correspondence, notices, and orders from the Board.

(~~a~~b) Each person ~~or approved program~~ holding a license ~~or approval~~ and ~~each person or program~~ who has an application on file with the ~~b~~Board shall notify the ~~b~~Board at its office of any and all changes of mailing address within thirty (30) calendar days after each change, giving both the old and new address.

(~~b~~c) If an address reported to the ~~b~~Board is a post office box, the licensee shall also provide the ~~b~~Board with a street address, but ~~he or she~~ they may request that the second address not be disclosed to the public.

(d) Each applicant and licensee who has an electronic mail address shall report to the Board that electronic mail address no later than July 1, 2022. The electronic mail address shall be considered confidential and not subject to public disclosure.

NOTE: Authority cited: Section 3510, Business and Professions Code. Reference: Sections 136 and 3522, Business and Professions Code.

Implementation of SB 697 regulation package

Using the Text language adopted by the Board, additions are shown by double underline, and deletions are indicated by ~~double strikethrough~~.

THIS SECTION MUST BE REMOVED FROM THIS REGULATION PACKAGE AS IT IS LOCKED, OR TOOMBSTONED, IN BPC SECTION 3502.1(e)(1)

1399.530. General Requirements for an Approved Program.

(a) A program for instruction of physician assistants shall meet the following requirements for approval:

(1) The educational program shall be established in educational institutions accredited by an accrediting agency recognized by Council for Higher Education Accreditation (''CHEA'') or its successor organization, or the U.S. Department of Education, Division of Accreditation, which are affiliated with clinical facilities that have been evaluated by the educational program.

(2) The educational program shall develop an evaluation mechanism to determine the effectiveness of its theoretical and clinical program.

(3) Course work shall carry academic credit; however, an educational program may enroll students who elect to complete such course work without academic credit.

(4) The medical director of the educational program shall be a physician and surgeon who holds a current license to practice medicine from any state or territory of the United States or, if the program is located in California, holds a current California license to practice medicine.

(5) The educational program shall require a three-month preceptorship for each student in the outpatient practice of a physician and surgeon or equivalent experience which may be integrated throughout the program or may occur as the final part of the educational program in accordance with Sections 1399.535 and 1399.536.

~~(6) Each program shall submit an annual report regarding it compliance with this section on a form provided by the board.~~

(b) Those educational programs accredited by the Accreditation Review Commission on Education for the Physician Assistant (''ARC-PA'') shall be deemed approved by the ~~b~~Board. Nothing in this section shall be construed to prohibit the ~~b~~Board from disapproving an educational program which does not comply with the requirements of this article. Approval under this section terminates automatically upon termination of an educational program's accreditation of ARC-PA.

NOTE: Authority cited: Section 3510, Business and Professions Code. Reference: Sections 3509 and 3513, Business and Professions Code

Using the Text language adopted by the Board, additions are shown by double underline, and deletions are indicated by ~~double strikethrough~~.

1399.540. Limitation on Medical Services.

(a) A PA may provide those medical services which they are authorized to perform, and which are consistent with the PA's education, training, and experience, and which are rendered under the supervision of a licensed physician and surgeon pursuant to a practice agreement in accordance with Section 3502 of the Business and Professions Code. ~~A physician assistant may only provide those medical services which he or she is they are competent to perform and which are consistent with the physician assistant's education, training, and experience, and which are delegated in writing by a supervising physician who is responsible for the patients cared for by that physician assistant.~~

(b) The writing which ~~delegates~~ defines the medical services the PA is authorized to perform shall be known as a ~~delegation of services~~ practice agreement. A ~~delegation of services~~ practice agreement shall be signed and dated by the ~~physician assistant~~ PA and one or more physicians and surgeons or a physician and surgeon who is authorized to approve the practice agreement on behalf of the physicians and surgeons on the staff of an organized health care system. ~~Each supervising physician. A delegation of services agreement may be signed by more than one supervising physician only if the same medical services have been delegated by each supervising physician. A physician assistant may provide medical services pursuant to more than one delegation of services agreement.~~

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

(d) A physician assistant shall consult with a physician and surgeon regarding any task, procedure or diagnostic problem which the physician assistant determines exceeds ~~his or her~~ their level of competence or shall refer such cases to a physician and surgeon.

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

UPDATED Revised Text

Implementation of SB 697 regulation package

Using the Text language adopted by the Board, additions are shown by double underline, and deletions are indicated by ~~double strikethrough~~.

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

In any setting, including for example, any licensed health facility, out-patient setting~~s~~, patients' residence~~s~~, residential facility~~ies~~, and hospice~~s~~, as applicable, a physician assistant may, pursuant to a~~delegation~~ practice agreement; ~~and protocols where present, protocols:~~

(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 and surgeon.

(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 surgeon 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)-(g), inclusive, of Section 3502.1 of the Code.

(i) (1) Perform surgical procedures without the personal presence of the supervising physician which are customarily performed under local anesthesia or procedural sedation.

UPDATED Revised Text

Implementation of SB 697 regulation package

Using the Text language adopted by the Board, additions are shown by double underline, and deletions are indicated by ~~double strikethrough~~.

Prior to delegating any ~~such~~ surgical procedures under local anesthesia, procedural sedation, or general anesthesia, the supervising physician ~~and surgeon~~ shall review the documentation which indicates that the physician assistant is trained to perform the surgical procedures. ~~All other s~~Surgical procedures requiring ~~other forms of~~ general anesthesia may be performed by a physician assistant only when ~~in the personal presence of a~~ the supervising physician is immediately available during the procedure ~~and surgeon~~.

(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 supervising physician is physically accessible and able to return to the patient, without any delay, upon the request of the physician assistant to address any situation requiring the supervising physician's services.

(j) ~~A physician assistant may perform informed~~ Obtain the necessary consent ~~about~~ for recommended treatments~~. In seeking a patient's authorization or agreement to undergo a specific medical treatment the physician assistant shall:~~

~~(1) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.~~

~~(2) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The information should include:~~

~~(A) the diagnosis;~~

~~(B) the nature and purpose of recommended interventions; and,~~

~~(C) the burdens, risks, and expected benefits of all options, including foregoing treatment.~~

~~(3) D~~and document the informed consent conversation and the patient's decision in the medical record.

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

Implementation of SB 697 regulation package

Using the Text language adopted by the Board, additions are shown by double underline, and deletions are indicated by ~~double strikethrough~~.

1399.545. Supervision Required.

(a) A supervising physician shall be available in person or by electronic communication at all times when the physician assistant is caring for patients. If the supervising physician is unable to provide this supervision, they may designate an alternate physician and surgeon with whom the physician assistant may consult. Should the alternate physician and surgeon be needed to supervise and consult with the physician assistant for a period exceeding three days (72 hours), the alternate supervising physician ~~should~~shall have a practice agreement in place with the physician assistant.

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

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

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

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

~~(1) Examination of the patient by a supervising physician the same day as care is given by the physician assistant~~ Within a new practice arrangement the supervising physician and the physician assistant shall meet monthly for the first six (6) months to discuss practice-relevant clinical issues and quality improvement measures~~;~~

~~(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~~ Within an existing practice arrangement the supervising physician and physician assistant shall meet at least once every six (6) months to discuss practice-relevant clinical issues and quality improvement measures~~;~~

(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 A written record of these meetings shall be signed and dated by both the supervising physician and the physician assistant and shall be available upon request by the Board. The written record shall include a description of the relevant clinical issues discussed and the quality improvement measures taken:~~

~~(4) Other mechanisms approved in advance by the board The supervising physician shall develop and enact a quality assurance program to maintain the standard of care that the physician assistant provides. An onsite inspection shall be conducted at least once every quarter (3 months) to monitor the quality of care being provided by the physician assistant.~~

(f) The supervising physician has continuing responsibility to follow the progress of the patient and to make sure that the physician assistant does not function independently~~autonomously~~. The supervising physician shall be responsible for all medical services provided by a physician assistant under ~~his or her~~ their supervision.

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

Implementation of SB 697 regulation package

Using the Text language adopted by the Board, additions are shown by double underline, and deletions are indicated by ~~double strikethrough~~.

1399.546. Reporting of Physician Assistant Supervision.

(a) When providing care to patients in a general acute care hospital as defined in Section 1250 of the Health and Safety Code, ~~E~~each time a physician assistant provides care for a patient and enters ~~his or her~~ their name, signature, initials, or computer code on a patient's record, chart, or written order, the physician assistant shall also record in the medical record for that episode of care the supervising physician who is responsible for the patient state the name of the supervising physician responsible for the patient.

b) If the electronic medical record software used by the physician assistant is designed to, and actually does, enter the name of the supervising physician for each episode of care into the patient's medical record, such automatic entry shall be sufficient for compliance with this recordkeeping requirement.

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