

 BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
 GAVIN NEWSOM, GOVERNOR

 DEPARTMENT OF CONSUMER AFFAIRS
 PHYSICIAN ASSISTANT BOARD

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MEMORANDUM

| DATE | November 8, 2021 |
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| то | Physician Assistant Board |
| FROM | Jasmine Dhillon, Legislative/Regulatory Analyst |
| | Karen Halbo, Regulations Counsel, Attorney III |
| SUBJECT | Agenda Item 15A. Regulatory Update November 2021 |

Background

Senate Bill (SB) 697 (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 amend 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). At the November 9, 2020, the Board determined that 16 CCR sections1399.530, 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. For that reason, those sections were removed from the rulemaking. The approved changes were thereafter split into two regulatory packages: -*SB 697 Implementation,* which concerned physician practice and required the California Medical Board's approval and -*Applications, Exam Scores, Addresses & Recordkeeping*.

The Medical Board at a May 14, 2021 meeting approved PAB's proposed regulatory language for the *SB 697 Implementation* regulation package. Subsequent to that meeting, the Department of Consumer Affairs (DCA) Legal Affairs Division (LAD) gave an elevated review to the text language for both regulation packages and recommended removal of text portions that repeated statutory language if the duplication could not be justified.

On July 23, 2021, the California Academy of PAs (CAPA) sent the Board a letter raising additional concerns about both proposed regulation packages. 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 CAPA's concerns. On October 13, 2021, those individuals met with representatives from CAPA and discussed CAPA's concerns. Those individuals held additional meetings after meeting with CAPA and are providing amended text draft for the Board's consideration.



This Memo discusses the proposed changes to the text of both SB 697 related regulation packages. Text already adopted by the Board has been marked with double strikethrough to show deletions and double-underline to show additions to the proposed language the Board already adopted. As such changes can be difficult to follow, the changes have also been marked with yellow high-lighting and in italics. A clean copy of both texts is also attached so the Board can see clearly what the language will look like when published for public comment.

Changes Made to the SB 697 Implementation regulation text: 16 CCR sections 1399.502, 1399.540, 1399.541, and 1399.545

16 CCR section 1399.502 – Definitions. In seeking to explain replacing the delegation of services agreement with a practice agreement, the previously approved language had repeated definitions of terms already defined in statute, without justification for the duplication. Per LAD's request, the definitions repeating statute were struck or revised to cite the relevant statute. The changes made are:

- subdivisions (c), (d), and (f) were struck as those terms are already defined in Business and Professions Code (BPC) section 3501.
- subdivision (e) was relabeled subdivision (c)
- subdivision (g) was relabeled as subdivision (d)
- subdivision (i) was relabeled as subdivision (e) and edited to clarify that the mandatory elements of a practice agreement are in BPC section 3502.3
- subdivision (f) was added to clarify that supervision is defined in BPC section 3501(f).

16 CCR section 1399.540 - Limitation on Medical Services.

- In subdivision (b), the first sentence was deleted as unnecessary and removed to make the subdivision easier to follow. The remaining sentence that now constitutes subdivision (b) is necessary to clarify the significant change made by replacing the delegation of services model with the practice agreement model. A PA previously had a delegation of services agreement with one physician only and now a PA may enter into a practice agreement with a group of physicians and work with all of the physicians in the group under that one practice agreement. While this is spelled out in BPC section 3502.3(a)(2)(B), this significant change is restated here for clarity.
- In subdivision (d), the subdivision was re-written to require a PA faced with a task beyond their abilities to either consult with a supervising physician or refer the patient to a licensed healthcare provider competent to render the services needed. CAPA pointed out that the language as adopted required the PA to refer patients requiring services beyond the PA's ability to make a referral to a physician only. This requirement goes beyond the existing standard of care, under which PA presently, when appropriate, refer patients to individuals who are not physicians, but are licensed healthcare providers, such as a dentist, podiatrist, or a patient's treating psychologist or therapist.
- Additional reference citations were added to the Note.



16 CCR section 1399.541 - Medical Services Performable,

- In subdivision (i)(1) minor grammatical changes were made for clarity, and the term "evidence" was substituted for "documentation" so that a supervising physician may review their own experiences with a PA in order to determine the PA is qualified to perform surgical procedures under general anesthesia.
- In subdivision (i)(2), the definition of "immediately available" was struck and moved to be subdivision (i)(3)
- Subdivision (j) revises former subdivision (j)(3), rewording it to fit within the list structure set out by the sentence just preceding subdivision (a)
- Subdivision (k) is added to make clear the list of what a PA may do under a
 practice agreement set out in this regulation section is not exhaustive, and that
 other services may be provided. Examples of services not specified in this list that
 a PA could be allowed to provide per a practice agreement would include COVID19 vaccinations or booster shots. This subdivision is added to make clear it is the
 practice agreement that determines the PA's practice, not the list in this regulation
 section.
- Former subdivision (j) has been deleted in its entirety and items within it moved to other subdivisions.

16 CCR section 1399.545 – Supervision Required

- Subdivision (a) was revised to clarify the supervising physician must be available for a PA's inquiries in person, by phone, or other means of electronic communication when a PA is providing medical services for patients. The rest of the subdivision was removed after CAPA pointed out that the previously adopted language about who will cover when a supervising physician is unavailable is better left to be addressed in the practice agreement.
- Subdivisions (b) and (c) were also pointed out by CAPA to be better addressed by the PA and the supervising physician in the practice agreement and were removed.
- Former subdivision (d) is relabeled as subdivision (b) and edited for clarity. It is an important consumer protection that a PA knows what procedures must be followed in an emergency well before an emergency situation arises. The statutory changes made by SB 697 did not address this issue. Depending on where a PA works emergency procedures may already be established, but all PAs need to have a clear plan to follow of what steps to take when an emergency beyond their training and competency occurs. To meet the Board's consumer protection mandate, this subdivision requires the practice agreement address these procedures.
- All of former subdivision (e) is being struck, not just paragraphs (e)(1) & (2), as these were pointed out by CAPA as matters that are best left to the PA and the supervising physician to address in the practice agreement.
- Former subdivision (f) is relabeled as subdivision (c) and the word "autonomously" is replaced with the phrase "without supervision" for clarity.



Changes made to the Applications, Exams, Addresses, & Recordkeeping regulation text: 16 CCR sections 1399.506, 1399.507, 1399.511, and 1399.546

16 CCR section 1399.506 - Applications for Licensure

In the existing regulations, neither the information that is required of an applicant was listed in regulation, nor was a form incorporated by reference. Since the board adopted this section, only the following minor grammatical changes have been made:

- subdivision (a), the term "associated" was removed because the term was vague, not defined, and not necessary.
- subdivision (d) a minor grammatical change was made to use the term "application" instead of "licensure."
- subdivisions (e) and (f) references to "section" were corrected to read "subdivision."

16 CCR section 1399.507 - Examination Required

There were no changes made to the text the Board has already adopted.

In 16 CCR section 1399.511 - Address of Record

Since the board adopted this section, only the following changes have been made:

- "valid" was removed as vague, undefined, and not necessary
- the "s" on "service" in the phrase "service of ..." was deleted
- subdivision (c) was deleted as unnecessary
- subdivision (d) was deleted. As a general rule, DCA Boards cannot require individuals to provide electronic mail addresses, however PAB invites applicants to voluntarily provide this information as a part of their application.

16 CCR 1399.546 - Reporting of Physician Assistant Supervision

Upon CAPA's recommendation, this section was deleted in its entirety (repealed) as unnecessary and placing procedures in regulation that are better addressed by the PA and the supervising physician within the practice agreement.

Action Requested

The Board is asked to make two motions amending the text of both SB 697 packages (*SB 697 Implementation* and *Applications, Exams, Addresses and Recordkeeping*) to reflect the changes described above. Attachment 1 shows the proposed changes highlighted, italicized, double underlined and double struck-out on the texts previously adopted by the Board. Attachment 2 shows a clean version of both texts, so the Board can see how the regulatory proposal will look when sent out for public notice.

<u>Motion 1:</u> Move to amend the text language in the *SB 697 Implementation* regulation package 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.

<u>Motion 2:</u> Move to amend the text language in the *Applications, Exams, Addresses and Recordkeeping* regulation package 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. CAPA's July 23, 2021 letter to the Board
- 2. Revised texts that show the changes from the previously adopted language highlighted, in italics, with double underline and double strikeout for the:
 - a. SB 697 Implementation regulation package amending 16 CCR sections 1399.502, 1399.540, 1399.541, and 1399.545
 - b. *Applications, Exams, Addresses and Recordkeeping* regulation package amending 16 CCR sections 1399.506, 1399.507, 1399.511, and 1399.546.
- 3. Clean versions of the amended text for the:
 - a. SB 697 Implementation regulation package amending 16 CCR sections 1399.502, 1399.540, 1399.541, and 1399.545
 - b. *Applications, Exams, Addresses and Recordkeeping* regulation package amending 16 CCR sections 1399.506, 1399.507, 1399.511, and 1399.546





July 23, 2021

The Honorable Juan Armenta President, Physician Assistant Board Hon. Members of the Board 2005 Evergreen Street, Suite 2250 Sacramento, CA 95815

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

RE: CAPA Proposed Regulatory Language to Implement SB 697

Dear President Armenta and Honorable Board Members:

On behalf of the 14,000 physician assistants (PAs) licensed in California, the California Academy of PAs (CAPA) is pleased to offer the Physician Assistant Board (PAB) its suggestions for the implementation of SB 697. This letter is in reference to the proposed regulatory language as found in the January 28, 2021 memorandum by the Physician Assistant Board.

For section <u>1399.502 Definitions</u>, CAPA supports the Board's recommended changes.

For section <u>1399.506 Filing of Applications for Licensure</u>, CAPA offers the following proposed amendments to subdivision (e) and offers a suggestion to (f). We acknowledge that the PAB had already expressed its desire to internally discuss the provisions of (e) which, as written, requires an applicant to disclose "any malpractice history," which is overly broad and could be interpreted to include malpractice lawsuits against the applicant that were dismissed, dismissed with prejudice, or frivolous.

Subdivision (e) PAB Proposed Language:

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

CAPA Respectfully Suggests:

(e) As a condition of licensure, an applicant shall disclose whether they have any malpractice history. For purposes of this section, "malpractice history" means:
(1) Civil judgments as described in Business & Professions Code section 803.1(b)(1).
(2) Malpractice settlements as described in Business & Professions Code section 801.01(a)(1).

This would be consistent with the required reporting to the National Practitioner Data Bank.

Subdivision (f) PAB Proposed Language:

(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.

CAPA respectfully suggests that the PAB include a definition or clarify the intended scope of "formal disciplinary history". Would this include academic probation for a failed test, or tardiness to a class or rotation?

CAPA Respectfully Suggests:

(f) As a condition of licensure, an applicant shall disclose whether they have any formal disciplinary history. For purposes of this section, formal disciplinary history means: (1) suspension, expulsion, or probation imposed by a physician assistant training program, or (2) suspension, revocation, probation, limitations on practice, citation, fine, or public reprimand by any authority issuing licenses, registrations, or certifications issued by any state. An applicant may as part of their application provide a written statement explaining any information provided pursuant to subparagraphs (1) and (2).

For reference, see Business & Professions Code section 803.1(a) which outlines required disclosures from the Board to an inquiring member of the public.

For section <u>1399.507 Examination Required</u>, CAPA supports the Board's recommended changes.

For section <u>1399.511</u>. Notice of Change of Address of Record, CAPA supports the Board's recommended changes. It may be valuable to include a clarifying note within the application for licensure discouraging use of the school's mailing address, as this has been a reported concern to program directors by the Board.

For section <u>1399.530 General Requirements for an Approved Program</u>, which currently is tombstoned by section 3502.1(e)(1) of the Code, CAPA supports the recommended changes when the Board can do so.

For section <u>1399.540 Limitation on Medical Services</u>, CAPA offers the following proposed amendments to subdivision (d).

Subdivision (d) PAB Proposed Language:

(d) A physician assistant shall consult with a physician <u>and surgeon</u> 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 <u>and surgeon</u>.

CAPA Respectfully Suggests:

(d) A physician assistant shall consult with a physician <u>and surgeon</u> regarding any task, procedure or diagnostic problem which the physician assistant determines exceeds his or her <u>their</u> level of competence or shall refer such cases to <u>the appropriate licensed healthcare</u> <u>provider a physician <u>and surgeon</u></u>.

Prior regulatory language was written under the model of an individual physician delegating their authority to an individual physician assistant on a task-by-task basis, who, absent that delegation, lacked their own medical authority. This framework underwent a fundamental paradigm shift with the enactment of SB 697. In some instances, a physician and surgeon may not be the only appropriate

provider for the referral. Here is an easy example: A dental abscess may need to be referred to dentistry, a foot ulcer to podiatry, wound care to a registered nurse, or a mental health disorder to mental health provider. This existing regulation that requires a PA to *only* refer patients to a physician and surgeon is easily demonstrated to go against the standard of care and does not match the legislative intent of SB 697.

This example proves the broader point under SB 697, and why its paradigm shift makes practical sense. A supervising physician and a PA both have their own competencies based on their own training and experience. Thus, both in real-life applications within an integrated health care system, and under SB 697's flexible practice agreement approach, a physician may *not* be the most appropriate party for a PA to refer a patient to based upon standard of care. Furthermore, SB 697 in section 3502.3 of the Code mandates in subdivision (b) that the practice agreement address the issue of consultations and referrals.

For section <u>1399.541</u>. <u>Medical Services Performable</u>, CAPA offers the following proposed amendments in the body, and subdivision (a) and (i).

PAB Proposed Language:

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 settings, patients' residences, residential facilityies, and hospices, as applicable, a physician assistant may, pursuant to a delegation practice agreement: and protocols where present, protocols:

CAPA Respectfully Suggests:

A PA may, pursuant to Business & Professions Code section 3502 (a)(1) through (4) initiate an order or perform a task, which shall be considered the same as if they had been ordered or performed by a supervising physician, without any prior patient specific order of a supervising physician.

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

The existing regulatory language was clearly written under the premise of the repealed and disfavored delegation of services agreement model. The regulation should reiterate both the permitted scope of what a PA may do and the limitations upon what a PA may do as reflected in the statute referenced. Importantly, the term "the supervising physician" is distinctly different from "a supervising physician". Binding statute permits a PA to have more than one supervising physician and the regulations, to be lawful, cannot contradict the statute. First, this makes common sense as a PA may have different physician supervisors not only in sequence, on different days, and the word "the" cannot differentiate between them clearly. Second, as discussed above, as PAs and physicians have different areas of expertise, a PA may during a single day could be appropriately supervised by

different physicians for different patients presenting with different ailments. And third, because of points one and two, this is what the Code says. Consider the definition of Practice Agreement¹ and you will see it is not restrained to a single physician, but embraces "one or more" professionals, mentions "physicians and surgeons" in the plural, and mentions the staff, all of whom either individually or collectively, pursuant to the terms of the practice agreement, may lawfully be a PA's supervisors, again depending on who the physicians are and who the PAs are, what they are each capable of doing, and what kind of patients they see on any given day.

On subdivision (a), CAPA noted that the subdivision referenced should be updated to note the additional informed consent provision in (j), corrected to read "for those services described in Section 1399.541(b) through Section 1399.541(ij)."

Subdivision (i) PAB Proposed Language:

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

CAPA Respectfully Suggests:

(i) (1) Perform surgical procedures without the personal presence of the <u>a</u> supervising physician which are customarily performed under local anesthesia <u>or procedural sedation</u>. Prior to delegating any <u>a PA performing such</u> surgical procedures <u>under local anesthesia</u>, <u>procedural sedation</u>, or general anesthesia, the <u>a</u> supervising physician and surgeon shall review the documentation which indicates that the physician assistant is trained to perform the surgical procedures. All other sSurgical procedures requiring other forms of general anesthesia may be performed by a physician assistant only <u>when</u> in the personal presence of a the <u>a</u> supervising physician is immediately available during the procedure and surgeon. "Immediately available" means a supervising physician is physically accessible and able to attend to the patient, without any delay, upon the request of the physician assistant to address any situation requiring a supervising physician's services.

(2) A physician assistant may also act as first or second assistant in surgery under

¹ (k) "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 physician assistants in any other law shall have the same meaning as a practice agreement.

the supervision of a supervising physician. The physician assistant may so act without the personal presence of the <u>a</u> supervising physician if the <u>a</u> supervising physician is immediately available to the physician assistant. "Immediately available" means the <u>a supervising</u> 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 <u>a</u> supervising physician's services.

The existing regulatory language was, again, clearly written under the premise of a delegation of services agreement. The reference to "delegating to" in (i)(1) therefore must clearly be stricken. Again, we believe that SB 697 highlights a paradigm shift that it is the legislative intent that "a supervising physician" oversees the practice of the PA, and respectfully ask that "the supervising physician" be replaced with "a supervising physician" to match that intent. As a note of proper procedure, the term "immediately available" is undefined in its first reference of (i)(1) and should be included. While we maintain that SB 697 states in clear language that supervision "shall not be construed to require the physical presence of the physician and surgeon", we commend the PAB for its attempt at offering a balanced approach in navigating a regulatory clarification of what it deems to be the minimum acceptable level of supervision in the high-risk nature of general anesthesia procedures.

For section <u>1399.545</u>. Supervision Required, CAPA offers the following amendments to subdivisions (a), (b), (c), (d), (e) and (f).

Subdivision (a) PAB Proposed Language:

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

CAPA Respectfully Suggests:

(a) A supervising physician shall be available in person or by electronic communication at all times when the physician assistant is caring for patients. <u>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.</u>

All of the stricken language is unlawful as it abrogates the practice agreement model established by SB 697 where these issues are decided by professionals based on what they know their workload, needs, and capacities to be. Indeed, this proposed regulation unlawfully implements a mechanism wherein a PA could practice without a practice agreement. SB 697 is clear; a physician shall adhere to adequate supervision as agreed to and as solely governed by the practice agreement if that agreement is lawful. The law is unambiguous on this point, and the mechanism proposed by the PAB is likely to result in unsupervised PA practice fraught with abuse of this regulatory language. Therefore, we believe the language must be stricken.

Subdivision (b) PAB Proposed Language:

(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.

CAPA Respectfully Suggests:

(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.

This unamended regulation unlawfully contradicts Black letter law, for the reasons described above. Not only does it obviously refer to the repealed delegation of services agreement model, but it is also in perfect and total contradiction with the statute's practice agreement provisions. The plain language of statute is clear: a PA can lawfully perform services which they, in themselves, are competent to perform, and consistent with the PA's education, training, and experience, pursuant to the terms of an agreement crafted by those who know what needs to be done by whom when. Moreover, when the PAB offered its unqualified support for a signature of SB 697, it did so with full knowledge that its proposed amendment that would have codified this language was rejected.

Furthermore, this is terrible – said bluntly, arrogant -- public policy. Consider first the use of the word "specialty." With respect, neither the PAB nor its staff are qualified to be the sole judge of whether two licensees are "specialists" (whatever that means, it is undefined) expert in the tasks they are performing when the two licensees (i) have unlimited and plenary licenses that permit them to perform tasks whether or not they have an official "specialist" designation, (ii) whose "specialties" (undefined) and competencies evolve over time as a result of practical experience, and (iii) where expert specialty is not uniformly verified based upon specialty certifications or exams. This is why, when a physician is offered as a medical expert in a civil case, they must be individually qualified as an expert – because there is no universally accepted test or basis upon which to determine a physician's specialty expertise.

Next, consider the phrase, "usual and customary practice." This is just not how plenary licenses work. Under this standard, a lawyer who was an immigration law expert would not be permitted to take a client in a slip and fall case. The lawyer would never be permitted to anything new within the scope of their license, i.e., not "usual and customary" for the lawyer's practice. With deep respect, this is not how medicine works either. Physicians and PAs are always doing new things – that is, in fact, how they become "specialists," – by doing something they have never done before and doing it over and over again. To say that a PA can only perform those tasks that are "usual and customary" for a physician misapprehends at the root how plenary licenses work generally, and how medicine works in practice particularly.

This is not to suggest that SB 697 permits PAs *carte blanche* in their practice, or denies PAB objective, patient-protecting criteria for determining that a PA practiced beyond their capacities. Regardless of the practice agreement, a PA cannot perform a service for which they are not competent to perform, or lack the sufficient education, training, and experience. In those instances, the PAB is qualified to discipline PAs accordingly. (See, e.g., Business & Professions Code section 3502)

Subdivision (c) PAB Proposed Language:

(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.

CAPA Respectfully Suggests:

(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. A practice agreement shall address the methods for the continuing evaluation of the competency and qualifications of the physician assistant.

The existing regulatory language was again clearly written under the premise of a delegation of services agreement. The reference to "delegating to" therefore must be stricken. SB 697 requires that a practice agreement shall address the continuing evaluation of competency and qualifications of the PA.

Subdivision (d) PAB Proposed Language:

(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.

CAPA Respectfully Suggests:

(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. A practice agreement shall address 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.

The existing regulatory language was again clearly written under the premise of a delegation of services agreement, for when the supervising physician "is not on the premises". "Written transport" procedures are not mandated by SB 697. Rather, the law requires that the practice agreement needs to address the above referenced section, hereby incorporated into the regulatory language, which includes the appropriate consultation and referral process. That is for the practice to decide what process should occur.

Subdivision (e) PAB Proposed Language, in part:

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

The existing regulatory language was again clearly written under the premise of a delegation of services agreement and mandatory chart co-signature. CAPA believes this entire section should be stricken, as in our proposed amendment to (c), we include "A practice agreement shall address the methods for the continuing evaluation of the competency and qualifications of the physician assistant," which covers the language here.

Subdivision (f) PAB Proposed Language:

(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 <u>independently</u> autonomously. The supervising physician shall be responsible for all medical services provided by a physician assistant under <u>his or her their</u> supervision.

CAPA Respectfully Suggests:

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

See discussions above.

For section <u>1399.546</u>. Reporting of Physician Assistant Supervision, CAPA offers the following amendments to subdivision (a) and (b).

Subdivision (a) and (b) PAB Proposed Language:

(a) <u>When providing care to patients in a general acute care hospital as defined in</u> <u>Section 1250 of the Health and Safety Code</u>, <u>Ee</u>ach time a physician assistant provides care for a patient and enters <u>his or her their</u> 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.

CAPA Respectfully Suggests:

(a) <u>When providing care to patients in a general acute care hospital as defined in</u> <u>Section 1250 of the Health and Safety Code</u>, <u>Eeach time a physician assistant provides</u> care for a patient and enters his or her <u>their</u> name, signature, initials, or computer code on a patient's record, chart, or written order, the physician assistant shall <u>have also</u> record<u>ed</u> in the medical record<u>or</u> or by the mechanism established in the practice agreement<u>for</u> for that episode of care the supervising physician who is responsible for the patient state the name of the <u>a</u> 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 <u>a</u> 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.

The existing regulatory language was again clearly written under the premise of a delegation of services agreement, wherein each encounter was an instance of authority delegated to the PA by their supervising physician. The requirement found in 3502(f) of the Code, states that the practice agreement shall establish a mechanism to identify a supervising physician while a PA is rendering services in an acute care hospital. Regulations cannot contradict the Legislature's decree that such matters be resolved by the parties in a practice agreement. The stricken language is exactly contradictory to statute.

Conclusion

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

Very truly yours,

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

DEPARTMENT OF CONSUMER AFFAIRS Title 16. PHYSICIAN ASSISTANT BOARD

PROPOSED REGULATORY LANGUAGE SB 697 Implementation

| Legend: | Added text is indicated with an <u>underline</u> . |
|---------|--|
| | Omitted text is indicated by (* * * *) |
| | Deleted text is indicated by strikeout. |

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

§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 bBoard as a physician assistant.

—(d) "Traince" 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

(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. (<u>hd</u>) "Approved controlled substance education course" means an educational course approved by the b<u>B</u>oard pursuant to section 1399.610.

(ig) "Practice agreement" means the definition set forth writing described in Section 3501(k) and it must contain the elements described in Section 3502.32, 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 physician assistants in any other law shall have the same meaning as a practice agreement.

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

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) <u>A physician assistant may provide those medical services which they are</u> <u>authorized to perform, which are consistent with the physician assistant's education,</u> <u>training, and experience, and which are rendered under the supervision of a licensed</u> <u>physician and surgeon pursuant to a practice agreement in accordance with Section</u> <u>3502.3 of the Business and Professions Code.</u> A physician assistant may only provide those medical services which he or she is <u>they are</u> 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 <u>defines</u> the medical services <u>the physician assistant is</u> <u>authorized to perform shall be known as a delegation of services practice agreement.</u> A delegation of services <u>practice</u> agreement shall be signed and dated by the <u>physician assistant physician assistant</u> and <u>one or more physicians and surgeons or a physician</u> and surgeon who is authorized to approve the practice agreement on behalf of the <u>physicians and surgeons on the staff of an organized health care system in accordance</u> 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 Medical Board of California or their representative may require proof or demonstration of competence from any physician assistant for any tasks, procedures or management <u>he or she is they are</u> performing.

(d) A physician assistant shall consult with a physician <u>and surgeon</u> regarding any task, procedure, or diagnostic problem which the physician assistant determines exceeds his or her <u>their own</u> level of competence or shall refer such cases to a physician and surgeon qualified to undertake the task, procedure, or diagnosis. 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.

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

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 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.

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, 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 <u>a</u> physician <u>and surgeon</u>.

(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.

(d) Recognize and evaluate situations which call for immediate attention of a physician <u>and surgeon</u> 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 <u>the a</u> supervising physician which are customarily performed under local anesthesia <u>or procedural</u> <u>sedation</u>. Prior to <u>a physician assistant performing delegating any such</u> surgical procedures <u>under local anesthesia</u>, procedural sedation, or general anesthesia, <u>the a</u> supervising physician and surgeon shall review <u>the documentationevidence</u> which indicates that the physician assistant is trained <u>and qualified</u> to perform the surgical procedures. <u>All other sS</u>urgical procedures requiring <u>other forms of general</u> anesthesia may be performed by a physician assistant only when in the personal presence of <u>the a</u> supervising physician <u>is immediately available during the procedure and surgeon</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 <u>a</u> 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.

<u>(k) Perform any other services authorized by the practice agreement for which the physician assistant is competent.</u>

<u>(i) A physician assistant may perform informed_Obtain the necessary_consent about_for</u> 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.

(<u>3) Dand d</u>ocument the informed consent conversation and the patient's decision

NOTE: Authority cited: Sections 2018, 3502 and 3510, Business and Professions Code. Reference: Sections 2058, <u>3501</u>, 3502, 3502.3, <u>and 3502.1</u>, <u>3502.3 and 3509</u>, 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 <u>to receive inquiries</u>, in person, <u>by</u> <u>telephone</u>, or <u>by-other</u> electronic communication at all times when the physician assistant is <u>providing medical services</u> caring for patients. <u>If the supervising physician is</u> <u>unable to provide this supervision, they may designate an alternate physician and</u> <u>surgeon with whom the physician assistant may consult. Should the alternate physician</u> <u>and surgeon be needed to supervise and consult with the physician assistant for a</u> <u>period exceeding three days (72 hours), the alternate supervising physician should shall</u> <u>have a practice agreement in place with the physician assistant</u>

(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 practice agreement 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 training and competency scope of practice. for such times when a supervising physician is not on the premises.

— (c) 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

(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 these 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.

(<u>c</u>f) <u>TheA</u> supervising physician has continuing responsibility to follow the progress of the patient and to make sure that the physician assistant does not function <u>without</u> <u>supervision_autonomously.</u> <u>TheA</u> supervising physician shall be responsible for all medical services provided by a physician assistant under <u>his or her their</u> supervision.

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

DEPARTMENT OF CONSUMER AFFAIRS Title 16. PHYSICIAN ASSISTANT BOARD

PROPOSED REGULATORY LANGUAGE

Applications, Exam Scores, Addresses & Recordkeeping

| Legend: | Added text is indicated with an <u>underline</u> . |
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| | Omitted text is indicated by (* * * *) |
| | Deleted text is indicated by strikeout. |

Amend Section 1399.506 of Article 1 of Division 13.8 of Title 16 of the California Code of Regulations

§1399.506. Filing of Applications for Licensure.

(a) Applications for <u>As a condition of initial</u> <u>To become</u> licens<u>edure</u> as a physician assistant shall be filed on a form provided by the board <u>an applicant must submit all</u> 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) 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. 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.

(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) While disclosure of status as a refugee, asylee, or having a special immigrant visa is voluntary, an applicant who was admitted to the United States as a refugee pursuant to section 1157 of title 8 of the United States Code, or was granted asylum by the Secretary of Homeland Security or the United States Attorney General pursuant to section 1158 of Title 8 of the United States Code, or has a special immigrant visa and was granted a status pursuant to section 1244 of Public Law 110-18, Public Law 109-163, or section 602(b) of title VI of division F of Public Law 111-8, relating to Iraqi and Afghan translators/interpreters or those who worked for or on behalf of the United States government and provides evidence of that status shall have their application review expedited pursuant to section 135.4 of the Code and the Physician Assistant Board may assist such an applicant with the application initial licensure process.

(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 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. For purposes of this <u>subdivision</u> "malpractice history" means:

(1) Civil judgments as described in section 803.1(b)(1) of the Code.

(2) Malpractice settlements as described in section 801.01(a)(1) of the Code.

(f) As a condition of licensure, an applicant shall disclose whether they have any history of discipline. For purposes of this subdivision section "history of discipline" means:

(1) suspension, expulsion, probation, or reprimand imposed by a physician assistant training program,

(2) suspension, revocation, probation, limitations on practice, citation, fine, public reprimand, letters of public reprimand or reproval, or any other informal or confidential discipline by any authority of any state issuing licenses, registrations, or certifications. An applicant may, as a part of their application provide a written statement explaining any information provided pursuant to subparagraphs (1) and (2).

NOTE: Authority cited: Sections <u>135.4</u>, 2018 and 3510, Business and Professions

Code. Reference: Sections <u>801.01, 803.1, 3509</u> and 3513, Business and Professions Code.

Amend Section 1399.507 of Article 1 of Division 13.8 of Title 16 of the California Code of Regulations

§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 hasve 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.

Amend Section 1399.511 of Article 1 of Division 13.8 of Title 16 of the California Code of Regulations

§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 service of all official correspondence, notices, and orders from the Board.

(a<u>b</u>) Each person or approved program holding a license or approval_and each person or program who has an application on file with the <u>b</u>Board shall notify the <u>b</u>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.

<u>(bc) If an address reported to the bBoard is a post office box, the licensee shall also provide the bBoard with a street address, but he or she they may request that the second address not be disclosed to the public.</u>

<u>(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 are later than July 1, 2022. The electro</u>

NOTE: Authority cited: Section 3510, Business and Professions Code. Reference: Sections 136 and 3523, Business and Professions Code.

Repeal Section 1399.546 of Article 4 of Division 13.8 of Title 16 of the California Code of Regulations

§1399.546. Reporting of Physician Assistant Supervision.

(a) E<u>each time a physician assistant provides care for a patient and enters his or her</u> 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 opisode of care the supervising physician who is responsible for the patient. When the physician assistant transmits an oral order, he or she they shall also state the name of the supervising physician 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.

DEPARTMENT OF CONSUMER AFFAIRS Title 16. PHYSICIAN ASSISTANT BOARD

PROPOSED REGULATORY LANGUAGE SB 697 Implementation

| Legend: | Added text is indicated with an <u>underline</u> . |
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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 bBoard 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 Caifornia

(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.

(hd) "Approved controlled substance education course" means an educational course approved by the bBoard pursuant to section 1399.610.

(ie)"Practice agreement" means the definition set forth in Section 3501(k) and it must contain the elements described in Section 3502.3.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 physician assistants in any other law shall have the same meaning as a practice agreement.

(f) <u>"Supervision" means the definition set forth in Section 3501(f).</u>

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) <u>A physician assistant may provide those medical services which they are</u> <u>authorized to perform, which are consistent with the physician assistant's education,</u> <u>training, and experience, and which are rendered under the supervision of a licensed</u> <u>physician and surgeon pursuant to a practice agreement in accordance with Section</u> <u>3502.3 of the Business and Professions Code.</u> 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 the medical services shall be known as a delegation of services agreement. A delegation of services practice agreement shall be signed and dated by the physician assistant 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 Medical Board of California or their representative may require proof or demonstration of competence from any physician assistant for any tasks, procedures or management <u>he or she is they 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 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.

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

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 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.

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, 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 <u>a</u> physician <u>and surgeon</u>.

(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.

(d) Recognize and evaluate situations which call for immediate attention of a physician <u>and surgeon</u> 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 <u>thea</u> supervising physician which are customarily performed under local anesthesia <u>or procedural</u> <u>sedation</u>. Prior to <u>a physician assistant performing delegating any such</u> surgical procedures <u>under local anesthesia</u>, procedural sedation, or general anesthesia, <u>thea</u> supervising physician and <u>surgeon</u> shall review <u>the documentationevidence</u> which indicates that the physician assistant is trained <u>and qualified</u> to perform the surgical procedures. <u>All other sS</u>urgical procedures requiring <u>other forms of general</u> anesthesia may be performed by a physician assistant only when in the personal presence of the <u>a</u> supervising physician <u>is immediately available during the procedure and surgeon</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 supervising physician if thea 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.

<u>(i) A physician assistant may perform informed_consent about for recommended</u> 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) 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, <u>3501</u>, 3502, 3502.3, and 3502.1, <u>3502.3 and 3509</u>, 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 providing medical services 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 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.

(db) The practice agreement 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 training and competency.scope of practice for such times when a supervising physician is not on the premises.

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

(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.

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

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

DEPARTMENT OF CONSUMER AFFAIRS Title 16. PHYSICIAN ASSISTANT BOARD

PROPOSED REGULATORY LANGUAGE

Applications, Exam Scores, Addresses & Recordkeeping

| Legend: | Added text is indicated with an <u>underline</u> . |
|---------|--|
| | Omitted text is indicated by (* * * *) |
| | Deleted text is indicated by strikeout. |

Amend Section 1399.506 of Article 1 of Division 13.8 of Title 16 of the California Code of Regulations

§1399.506. Filing of Applications for Licensure.

(a) Applications for <u>To become</u> licensedure 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 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) 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. 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.

(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) While disclosure of status as a refugee, asylee, or having a special immigrant visa is voluntary, an applicant who was admitted to the United States as a refugee pursuant to section 1157 of title 8 of the United States Code, or was granted asylum by the Secretary of Homeland Security or the United States Attorney General pursuant to section 1158 of Title 8 of the United States Code, or has a special immigrant visa and was granted a status pursuant to section 1244 of Public Law 110-18, Public Law 109-163, or section 602(b) of title VI of division F of Public Law 111-8, relating to Iraqi and Afghan translators/interpreters or those who worked for or on behalf of the United States government and provides evidence of that status shall have their application review expedited pursuant to section 135.4 of the Code and the Physician Assistant Board may assist such an applicant with the application process.

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

(f) As a condition of licensure, an applicant shall disclose whether they have any malpractice history. For purposes of this subdivision "malpractice history" means:

(1) Civil judgments as described in section 803.1(b)(1) of the Code.

(2) Malpractice settlements as described in section 801.01(a)(1) of the Code.

(g) As a condition of licensure, an applicant shall disclose whether they have any history of discipline. For purposes of this subdivision "history of discipline" means:

(1) suspension, expulsion, probation, or reprimand imposed by a physician assistant training program.

(2) suspension, revocation, probation, limitations on practice, citation, fine, public reprimand, letters of public reprimand or reproval, or any other informal or confidential discipline by any authority of any state issuing licenses, registrations, or certifications. An applicant may, as a part of their application provide a written statement explaining any information provided pursuant to subparagraphs (1) and (2).

NOTE: Authority cited: Sections <u>135.4</u>, 2018 and 3510, Business and Professions Code. Reference: Sections <u>801.01, 803.1</u>, 3509 and 3513, Business and Professions Code.

Amend Section 1399.507 of Article 1 of Division 13.8 of Title 16 of the California Code of Regulations

§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 hasve 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.

Amend Section 1399.511 of Article 1 of Division 13.8 of Title 16 of the California Code of Regulations

§1399.511. Notice of Change of Address of Record.

(a) Each person submitting an application for licensure to the Board must include a 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 service of all official correspondence, notices, and orders from the Board.

 $(a\underline{b})$ Each person or approved program holding a license or approval and each person or program who has an application on file with the $\underline{b}\underline{B}$ oard shall notify the $\underline{b}\underline{B}$ oard 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.

NOTE: Authority cited: Section 3510, Business and Professions Code. Reference: Sections 136 and 3523, Business and Professions Code.

Repeal Section 1399.546 of Article 4 of Division 13.8 of Title 16 of the California Code of Regulations

§1399.546. Reporting of Physician Assistant Supervision.

(a) 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. When the physician assistant transmits an oral order, he or she they shall also 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.