

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: May 10, 2021
ATTENTION: Members, Medical Board of California
SUBJECT: Physician Assistant Board Regulations
Implementation of SB 697 - Title 16 California Code of
Regulations, Sections 1399.502, 1399.540, 1399.541,
1399.545,
FROM: Kerrie Webb, Staff Counsel

REQUESTED ACTION:

After review and consideration of the proposed amendments to Title 16 California Code of Regulations, Sections 1399.502, 1399.540, 1399.541, 1399.545, make a motion to direct staff to work with the Physician Assistant Board (PAB) to take all steps necessary to initiate the rulemaking process; authorize staff to make any technical or non-substantive changes to the rulemaking package without returning to the Board; notice the 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.

BACKGROUND

Senate Bill 697 (SB) (Caballero, Chapter 707, Statutes of 2019) became effective on January 1, 2020, and made numerous changes to the Physician Assistant Practice Act (Act), which provides for licensure and regulation of physician assistants (PA) by the Physician Assistant Board (PAB).

Generally, SB 697 authorizes a PA 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 PA is competent to perform the medical services. The Act requires that a practice agreement between a PA and a physician and surgeon meet specified requirements, including that the agreement have policies and procedures to ensure adequate supervision of the PA, including, but not limited to, appropriate communication, availability, consultations, and referrals between a physician and surgeon and the PA in the provision of medical services. In addition, a practice agreement must establish policies and procedures to identify a physician and surgeon who is supervising a PA rendering services in a general acute care hospital.

The Act authorizes a PA to furnish or order a drug or device subject to specified requirements, including the furnishing or ordering be in accordance with the practice agreement and consistent with the PA's educational preparation or for which clinical competency has been established and maintained, and that the supervising physician and surgeon be available by telephone or other electronic communication method at the time the PA examines the patient. The Act authorizes the PA to furnish or order Schedule II or III controlled substances in accordance with the practice agreement or a

patient-specific order approved by the treating or supervising physician and requires completion of a controlled substances course by the PA's next renewal if the PA is authorized by a practice agreement to furnish Schedule II controlled substances and if the PA has a DEA registration.

In addition, SB 697 provides that any reference to a "delegation of services agreement" in any other law means "practice agreement" as defined.

The Act clarifies that supervision does not require the supervising physician to be physically present but does require adequate supervision as agreed to in the practice agreement and does require that the physician be available by telephone or other electronic communication method at the time the PA examines the patient. However, the Act also prohibits this provision from being 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 the imposition of discipline.

On February 8, 2021, the PAB approved the proposed language (attached), and directed staff to proceed with the rulemaking process. Because these proposed amendments deal with PA scope of practice and physician supervision, the Medical Board of California must approve these proposed changes, as well.

STAFF RECOMMENDATION:

Staff recommends the Board direct staff to work with the PAB and proceed with the proposed rulemaking.

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 .
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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" or "PA" means a person who is licensed by the ~~h~~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 ~~h~~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 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.

(gh) "Approved controlled substance education course" means an educational course approved by the 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 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.

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

§1399.540. Limitation on Medical Services.

(a) A 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 ~~h~~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.

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~~.

In any setting, including for example, any licensed health facility, out-patient settings, patients' residences, residential facilities, 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 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.

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.

~~(i) 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) Dand 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.

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 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 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;~~

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

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

~~review those cases which by diagnosis, problem, treatment or procedure represent, in his or her judgment, the most significant risk to the patient.~~

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

(f) 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.