MEDICAL BOARD OF CALIFORNIA

INITIAL STATEMENT OF REASONS

Hearing Date: **August 14, 2019**

Subject Matter of Proposed Regulations: Physician Assistant Supervision Required

Section Affected: Section 1399.545 of Title 16 of the California Code of Regulations

Specific Purpose of each adoption, amendment, or repeal:

1. Problem being addressed:

Physician Assistants (PAs) are licensed health care practitioners that perform authorized medical services under the supervision of a licensed physician and surgeon (physician) pursuant to Business and Professions Code section 3502.

Business and Professions Code section 3510 authorizes the Medical Board of California (Medical Board) to amend or adopt regulations under its jurisdiction, including regulations regarding the scope of practice for PAs. The Physician Assistant Board (PAB), a board within the jurisdiction of the Medical Board, is authorized to make recommendations to the Medical Board concerning the scope of practice for PAs under Business and Professions Code section 3509.

Existing law at Business and Professions Code section 3502 provides for regulation of PAs and authorizes a PA to perform medical services, as set forth by regulations, when those services are rendered under the supervision of a licensed physician.

Existing regulation at Title 16 of the California Code of Regulations section 1399.545 (section 1399.545) interprets Business and Professions Code section 3502 and sets forth the authorized supervision mechanisms for PAs. Section 1399.545(e)(3) currently requires the supervising physician to review, countersign, and date a sample consisting of, at a minimum, five (5) percent of the medical records of patients treated by the PA functioning under adopted protocols within 30 days of the date of treatment by the PA. The regulation also requires the supervising physician to select for review those cases that by diagnosis, problem, treatment, or procedure represent, in his or her judgment, the most significant risk to the patient.

However, effective January 1, 2016, Business and Professions Code sections 3502 and 3502.1 were amended with the enactment of Senate Bill (SB) 337 (Pavley, Chapter 536, Statutes of 2015). This bill revised recordkeeping and supervision requirements for PAs, and provided new supervision mechanism options. Due to the amendments to Business and Professions Code sections 3502 and 3502.1, many of the provisions in subdivision (e) of section 1399.545 have been rendered inconsistent or duplicative, and have created confusion among licensees regarding which supervision mechanisms apply.

Moreover, currently, section 1399.545 does not address the new supervision mechanisms for the supervising physician who has delegated authority to the PA to administer, provide, or issue a drug order to a patient for a Schedule II controlled substance, as set forth in Business and Professions Code section 3502.1(e). This proposal would address these issues and create a comprehensive list of all authorized supervision mechanisms in a single place.

Additionally, section 1399.545(e)(4) currently authorizes other supervision mechanisms approved in advance by the PAB. The proposed amendment will clarify that such approval must be in writing by the PAB.

Finally, the proposed amendments to section 1399.545(e) will make non-substantive changes to the numbering and lettering of that subdivision to improve clarity.

2. Anticipated benefits from this regulatory action:

This regulatory proposal will conform section 1399.545 to the amended Business and Professions Code section 3502 as established in SB 337. The proposed amendments will remove duplicative language and will reference the other supervision mechanisms that are now available through the implementation of SB 337. In addition, language is being added to describe the mechanism in Business and Professions Code section 3502.1 for the administration of Schedule II controlled substances. The benefit of the proposed changes is to alleviate confusion among licensees and other interested parties about the current supervision requirements and provide reference to the requirements in one convenient location.

Factual Basis/Rationale

Factual basis for the determination that each proposed amendment to section 1399.545 is reasonably necessary to address the problem for which it is proposed:

Existing law provides for regulation of PAs and authorizes a PA to perform medical services as set forth by regulations when those services are rendered under the supervision of a licensed physician pursuant to Business and Professions Code section 3502.

Currently, section 1399.545(e)(3) requires the supervising physician to review, countersign, and date a sample consisting of, at a minimum five (5) percent of the medical records of patients treated by the PA functioning under adopted protocols within 30 days of the date of treatment by the PA. The regulation requires the supervising physician to select for review those cases that by diagnosis, problem, treatment, or procedure represent, in his or her judgment, the most significant risk to the patient.

The proposed amendments to subdivision (e) of section 1399.545 would delete those duplicative supervision guidelines and mechanisms, and instead, add the authority for the additional supervision methods that a physician may use to supervise a PA.

Business and Professions Code section 3502.1 authorizes a PA, while under the supervision of a physician, to administer or provide medication to a patient, or transmit orally, or in writing on a patient's record or in a drug order, an order to a person who may lawfully furnish the medication or medical device. Business and Professions Code section 3502.1 prohibits a PA from administering, providing, or issuing a drug order to a patient for Schedule II through Schedule V controlled substances without advance approval by a supervising physician for that particular patient unless the PA has completed an education course that covers controlled substances and that meets approved standards. Business and Professions Code section 3502.1 requires that the medical record of any patient cared for by a PA for whom a PA's Schedule II drug order has been issued or carried out to be reviewed, countersigned, and dated by a supervising physician within seven (7) days.

Currently, section 1399.545 does not address the new supervision mechanisms for the supervising physician who has delegated authority to the PA to administer, provide, or issue a drug order to a patient for a Schedule II controlled substance, as set forth in Business and Professions Code section 3502.1(e).

This proposal would amend section 1399.545 to centralize all alternative medical records review mechanisms in one place, including those provided under Business and Professions Code section 3502.1. Moreover, the proposed amendments would clarify that the supervising physician may use alternative mechanisms of supervision. The proposed changes are necessary to help reduce licensee confusion and to ensure adequate supervision of PAs.

At the PAB's April 24, 2017 meeting, the members discussed amending section 1399.545 to conform to the implementation of SB 337 and directed staff to develop proposed language.

At the PAB's October 30, 2017 meeting, it was determined that with the enactment of SB 337, section 1399.545 needed to be amended to eliminate duplicative and inconsistent provisions and to reflect all mechanisms available under the current law for supervising a PA. Language was also added to describe the mechanism allowed under Business and Professions Code section 3502.1 for administration of Schedule II controlled substances. The PAB then authorized staff to take all steps necessary to initiate the rulemaking process with the proposed text.

Because this proposal could be interpreted as affecting the scope of practice for PAs, the PAB's staff sent the proposal to the Medical Board for review and approval. At its January 18, 2018 meeting, the Medical Board approved the proposed amendments to section 1399.545 and authorized staff to proceed with the rulemaking process.

Specifically, the PAB and the Medical Board propose the adoption of the following amendments to section 1399.545 for the following reasons:

(1) Adopt subsection (e)(1) to add "One of the supervision mechanisms authorized by Section 3502.1 of the Code if the PA has been delegated authority to administer, provide, or issue a drug order to a patient for Schedule II controlled substances, and"

Business and Professions Code section 3502(c)(1) requires a PA and his or her supervising physician to establish written guidelines for the adequate supervision of the PA, and the requirement may be satisfied by the supervising physician adopting protocols for some or all of the tasks performed by the PA. Business and Professions section 3502 sets forth minimum content requirements for those protocols including mechanisms for supervising specified tasks (e.g., issuing Schedule II controlled substances). Section 1399.545 was originally adopted to make it clear that the written guidelines must contain the mechanisms the supervising physician will be using to supervise the tasks delegated to the PA. It was intended to cover all authorized mechanisms. Nevertheless, the current language under section 1399.545 has not been updated to reflect all authorized mechanisms for supervision.

Business and Professions Code section 3502.1, subdivision (e), contains authorized mechanisms to ensure adequate supervision of the administration, provision, or issuance by a PA of a drug order to a patient for Schedule II controlled substances. Those mechanisms include:

1. The medical record of any patient cared for by a PA for whom the PA's Schedule II drug order has been issued or carried out shall be reviewed, countersigned, and dated by a supervising physician and surgeon within seven days.

2. If the PA has documentation evidencing the successful completion of an education course that covers controlled substances, and that controlled substance education course (A) meets the standards, including pharmacological content, established in Sections 1399.610 and 1399.612 of Title 16 of the California Code of Regulations, and (B) is provided either by an accredited continuing education provider or by an approved PA training program, the supervising physician and surgeon shall review, counter sign, and date, within seven days, a sample consisting of the medical records of at least 20 percent of the patients cared for by the PA for whom the PA's Schedule II drug order has been issued or carried out. Completion of the requirements set forth in this paragraph shall be verified and documented in the manner established in Section 1399.612 of Title 16 of the California Code of Regulations. PAs who have a certificate of completion of the course described in paragraph (2) of subdivision (c) shall be deemed to have met the education course requirement of this subdivision.

While section 1399.545 was originally intended to consolidate supervision mechanisms in a single place, the foregoing supervision requirements for PAs who have been delegated authority to issue Schedule II controlled substances have never been addressed by section 1399.545.

Supervision mechanisms for PAs who administer or issue Schedule II controlled substances are set forth in Business and Professions Code section 3502.1(e) already. However, by adding this new subdivision (e)(1) to section 1399.545, the licensees will have a single reference point for supervision requirements for those PAs who have been delegated authority to administer, provide, or issue a drug order to a patient for Schedule II controlled substances. Further, by adding the word "and" to the end of this provision, it makes it easier for licensees to understand that the supervision mechanisms for Schedule II controlled substances are in addition to the supervision mechanisms that are required for other types of tasks delegated to PAs.

(2) Added new subdivision (e)(2) "One or more of the following mechanisms:"

This proposal would renumber this subdivision by adding a new subdivision (e)(2), which is designed to make it easier for licensees to understand that "one or more" mechanisms must be included in the written guidelines for the supervision to be compliant with the PA Practice Act (Act).

(3) Renumbered subsection (e)(1), (2), and (3) to subsections (e)(2)(A), (B), and (C).

This proposal would renumber these subdivisions to make it easier to understand the mechanism options available for PA supervision under the Act.

(4) Amend subsection (e)(3) (renumbered as "(e)(2)(C)"), strike duplicative existing text, and add "Any mechanism authorized by Section 3502 of the Code; or"

Business and Professions Code section 3502(c)(1)(A)-(D) sets forth the minimum content requirements for supervision protocols. They include:

> (A) A protocol governing diagnosis and management shall, at a minimum, 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 provided to the patient.
>
> (B) A protocol governing procedures shall set forth the information to be provided to 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.
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> (C) Protocols shall be developed by the supervising physician and surgeon or adopted from, or referenced to, texts or other sources.
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> (D) Protocols shall be signed and dated by the supervising physician and surgeon and the PA.

Existing regulation at section 1399.545(e)(3) contains nearly identical text to the above-quoted text from the Code and it does not include any of the new types of supervision mechanisms that are now authorized by Business and Professions Code section 3502(c)(2), as described below.

SB 337 added new supervision mechanism options for supervising PAs to Business and Professions Code section 3502, and under subdivision (c)(2)(A), states the supervising physician shall use one or more of the following mechanisms to ensure adequate supervision of the PA functioning under the protocols:

> (i) The supervising physician and surgeon shall review, counter sign, and date a sample consisting of, at a minimum, 5 percent of the medical records of patients treated by the PA functioning under the protocols within 30 days of the date of treatment by the PA.
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> (ii) The supervising physician and surgeon and PA shall conduct a medical records review meeting at least once a month during at least 10 months of the year. During any month in which a medical records review meeting occurs, the supervising physician and surgeon and PA shall review an aggregate of at least 10 medical records of patients treated by the PA functioning under protocols. Documentation of medical records reviewed during the month shall be jointly signed and dated by the supervising physician and surgeon and the PA.
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> (iii) The supervising physician and surgeon shall review a sample of at least 10 medical records per month, at least 10 months during the year, using a combination of the countersignature mechanism described in clause (i) and the medical records review meeting mechanism described in clause (ii). During each month for which a sample is reviewed, at least one of the medical records in the sample shall be reviewed using the mechanism described in clause (i) and at least one of the medical records in the sample shall be reviewed using the mechanism described in clause (ii).

The Board proposes to offer a simplified approach to listing supervision mechanisms by cross-referencing the statutory section that contains all of the newer options and striking the duplicative text in subdivision (e) that essentially repeats some, but not all, of the requirements in Business and Professions Code section 3502. The existing text would be struck and "Any mechanism authorized by Section 3502 of the Code" would replace it. This revision would enhance reader understanding of the differing types of supervision mechanisms while reducing or eliminating redundancies.

Since Business and Professions Code section 3502(c)(3) permits the Board to "establish other alternative mechanisms for the adequate supervision of the PA," the Board has elected to retain the other supervision mechanism options in existing subdivisions of section 1399.545(e) to allow for greater choice and flexibility for licensees to meet minimum supervision requirements.

(5) <u>Amend subdivision (e)(4) (renumbered as "(e)(2)(D)"), and add the words "and in writing"</u>

The proposed amendment will clarify that "other mechanisms approved by the Board" must be in writing, thus ensuring the PAB has an official record of the specific

supervision mechanism approved for the particular licensee. This would help assist the PAB in documenting compliance with the supervision requirements in the Act.

Underlying Data

Technical, theoretical or empirical studies, reports, or documents relied upon (if any):

1. Minutes of the PAB's April 24, 2017 meeting.

2. Minutes of the PAB's October 30, 2017 meeting.

3. Staff Report dated January 3, 2018, Agenda Item #10 for January 18, 2018 Medical Board meeting.

4. Minutes of the Medical Board's January 18, 2018 meeting.

4. SB 337 (Pavley, Chapter 536, Statutes of 2015)

Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the following facts:

In 2016, statutory amendments enacted by SB 377 became effective, which added more options for complying with supervision requirements. This proposal seeks to provide licensees with one convenient list of all currently existing authority to demonstrate adequate supervision of PAs functioning under written protocols. In addition, it would clarify that all other supervision mechanisms approved by the PAB must be in writing. Since the proposal would simply update and eliminate duplicative existing standards and not impose any new mechanisms or requirements on supervisors of PAs, the Medical Board has determined that there will be no statewide adverse economic impact on businesses.

Economic Impact Assessment

This regulatory proposal will have the following effects:

It will not create or eliminate jobs within the State of California because the proposal would simply update and eliminate duplicative existing standards and not impose any new mechanisms or requirements on supervisors of PAs.

It will not create new business or eliminate existing businesses within the State of California because the proposal would simply update and eliminate duplicative existing standards and not impose any new mechanisms or requirements on supervisors of PAs.

It will not affect the expansion of businesses currently doing business within the State of California because the proposal would simply update and eliminate duplicative existing standards and not impose any new mechanisms or requirements on supervisors of PAs.

This regulatory proposal will benefit the health and welfare of California residents because the proposed amendment would help alleviate confusion among licensees and other interested parties regarding the requirements for supervision. Inconsistencies between the recent statutory amendments and the existing regulation have caused confusion about what supervision mechanisms are authorized by the Act. Revisions that update section 1399.545 and correct duplication and inconsistencies between the regulation and Business and Professions Code sections 3502 and 3502.1 would help resolve these issues.

This regulatory proposal will not affect worker safety because the proposal does not involve worker safety. The proposal would simply update and eliminate duplicative existing standards and not impose any new mechanisms or requirements on supervising physicians or PAs. Therefore, workplace standards would not be altered by this proposal.

This regulatory proposal will not affect the state's environment because it does not involve environmental issues. The proposal would simply update and eliminate duplicative existing standards and not impose any new mechanisms or requirements, therefore, the environment would not be affected.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. Set forth below are the alternatives which were considered and the reasons each alternative was rejected or accepted:

1. Not amend the regulation: This alternative was rejected because section 1399.545 does not conform to the amended Business and Professions Code sections 3502 and 3502.1 as established in SB 337.

2. Amend the regulation: This alternative was accepted because the PAB and the Medical Board determined that amending section 1399.545 to conform to changes in Business and Professions Code sections 3502 and 3502.1 as established in SB 337 would help alleviate confusion about supervision mechanisms. The proposed changes include removing duplicative language and ensuring the regulation refers to the other mechanisms that are now available through the implementation of SB

337. In addition, language is being added to describe the mechanism in Business and Professions Code section 3502.1 for the administration of Schedule II controlled substances. These amendments will update the regulation and provide convenient information to physicians and PAs about the current supervision requirements.