

TITLE 16. MEDICAL BOARD OF CALIFORNIA

NOTICE IS HEREBY GIVEN that the Medical Board of California (Medical Board) is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at Medical Board of California, 2005 Evergreen Street, Sacramento, CA 95815, at 9:00 a.m., on August 14, 2019.

Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Medical Board at identified addresses no later than on August 12, 2019, or must be received at the hearing. The Medical Board, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

AUTHORITY AND REFERENCE

Pursuant to the authority vested by Business and Professions Code sections 2018, 3502, and 3510, the Medical Board is considering amendments to Title 16 of the California Code of Regulations (CCR) section 1399.545 (section 1399.545). The proposed regulation implements, interprets, and makes specific Business and Professions Code sections 3502, 3502.1, and 3516.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 3510 authorizes the Physician Assistant Board (PAB) to adopt, amend, and repeal regulations that may be necessary to enable it to carry out the provisions of its practice act. Section 3510 also authorizes the Medical Board to amend or adopt regulations under its jurisdiction, including regulations regarding the scope of practice for physician assistants (PAs). The 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 under 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 and surgeon (physician).

Existing law under section 1399.545 interprets Business and Professions Code section 3502 and sets forth the authorized supervision mechanisms for PAs. Section 1399.545(e) 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, which may create 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.

Anticipated Benefits of the Proposed Regulation:

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.

Evaluation of Inconsistency/Incompatibility with Existing State Regulations:

During the process of developing these regulations and amendments, the Medical Board has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

DISCLOSURES REGARDING THE PROPOSED ACTION

The Medical Board has made the following initial determinations:

Mandate on local agencies and school districts: None

Cost or savings to any state agency: None

Cost to any local agency or school district which must be reimbursed in accordance with Government Code sections 17500 through 17630: None

Other nondiscretionary cost or savings imposed on local agencies: None

Cost or savings in federal funding to the state: None

Cost impacts on a representative private person or business: The Medical Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Statewide adverse economic impact directly affecting businesses and individuals: None

Significant effect on housing costs: None

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 337 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.

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.

Effect on Small Business:

The Medical Board has determined that the proposed regulation would not affect small businesses because the proposal would simply update and eliminate duplicative existing standards and not impose any new mechanisms or requirements on supervisors of PAs.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

This regulatory proposal will not create new businesses or jobs eliminate existing businesses, or jobs and 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 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 Physician Assistant Practice Act. Revisions that update section 1399.545 and eliminate duplicated language 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.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5, subdivision (a)(13), the Medical Board must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Medical Board invites interested persons to present statements or arguments with respect to alternatives to the proposed regulation at the scheduled hearing or during the written comment period.

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS AND RULEMAKING FILE

The Medical Board will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the address below. As of the date this notice is published in the Notice Register, the rulemaking file consists of this

notice, the proposed text of the regulation, the initial statement of reasons, if any, or other information which the rulemaking is based, including the PAB's April 24, 2017 meeting minutes, the PAB's October 30, 2017 meeting minutes, the Medical Board's January 18, 2018 meeting minutes, and SB 337 (Pavley, Chapter 536, Statutes of 2015).

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After holding the hearing and considering all timely and relevant comments received, the Medical Board may adopt the proposed regulations substantially as described in this notice. If the Medical Board makes modifications which are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the Medical Board adopts the regulation as revised. Please send requests for copies of any modified regulations to the attention of Anita Winslow at the address indicated below. The Medical Board will accept written comments on the modified regulation for 15 days after the date on which they are made available.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

Upon its completion, copies of the Final Statement of Reasons may be obtained by contacting Ms. Winslow at the address below.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulation in underline and strikeout can be accessed through the Medical Board's website at: [http://www.mbc.ca.gov/About Us/Laws/Proposed Regulations](http://www.mbc.ca.gov/About_Us/Laws/Proposed_Regulations) or through the PAB's website at www.pac.ca.gov.

CONTACT PERSONS

Inquiries concerning the proposed administrative action may be directed to:

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The backup contact person is:

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