

TITLE 16 MEDICAL BOARD OF CALIFORNIA

NOTICE IS HEREBY GIVEN that the Medical Board of California 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 Embassy Suites San Francisco Airport - Waterfront, 150 Anza Blvd, Burlingame, CA 94010, at 9:00 a.m., on February 7, 2014. 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 of California at its office not later than 5:00 p.m. on January 27, 2014, or must be received by the Medical Board of California at the hearing. The Medical Board of California, upon its own motion or at the instance 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 Sections 2018, 3502, and 3510 of the Business and Professions Code, and to implement, interpret or make specific Sections 2058, 3502, and 3502.1 of said Code, the Medical Board of California is considering changes to Division 13.8 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST

A. Informative Digest

The Board is proposing the following changes:

Amend Section 1399.541 in Article 4 of Division 13.8.

The existing regulation permits a physician assistant (PA) to act as a first or second assistant in surgery under the supervision of an approved supervising physician.

This proposal would permit a PA to act as a first or second assistant in surgery without the personal presence of the supervising physician if the supervising physician is immediately available to the PA. "Immediately available" means able to return to the patient, without delay, upon the request of the PA or to address any situation requiring the supervising physician's services.

This proposal would also delete the word, "approved" as a modifier to the supervising physician. Senate Bill 1981 (Stats. 1998, Chapter 736) repealed Business and Professions Code Section 3515. SB 1981 deleted the requirement that the Board review and approve applications for PA supervisors.

B. Policy Statement Overview/Anticipated Benefits of Proposal

The Board's highest priority is the protection of the public and the proposed regulations will provide protection of the people of California by updating and clarifying supervision requirements while a PA acts as a first or second assistant in surgery. This regulatory proposal benefits the health and welfare of California residents because it represents the current standard of practice within the medical community, and will enhance consumer protection by allowing better access to care while still protecting the consumer. This proposal would permit the physician to address other patient needs while authorized PA services are being performed. Under this proposal the physician is still responsible for supervising the PA and is required to be "immediately available" to the PA, if needed, at the request of the PA or to address any situation requiring the supervising physician's services.

C. Consistency and Compatibility with Existing State Regulations

After conducting a review for similar regulations, the Board has found that these are the only regulations concerning this subject area. Therefore, the Board has determined that the proposed regulatory changes are neither inconsistent nor incompatible with existing regulations.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Sections 17500 - 17630 Require Reimbursement: None.

Business Impact

The Medical Board of California has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the following facts or evidence/documents/testimony:

The Medical Board regulates physicians and surgeons in the State of California, and the Physician Assistant Board, within the jurisdiction of the Medical Board, regulates PAs. The Medical Board currently has approximately 128,641 licensees and the Physician Assistant Board has

approximately 9,101 licensees for FY 2012-2013. PAs work in a variety of practice settings and specialties under the supervision of licensed physicians. The boards do not have data on either the number of physicians who supervise PAs by practice setting or the number of PAs who work as first or second assistants in surgery.

This regulation will clarify supervision requirements for PAs and supervising physicians as to the availability of the supervising physician when PAs are acting as first or second assistants in surgery. However, according to comments received at public board meetings, this proposed regulatory change represents the current evolution of the standard of practice within the medical community and, therefore, it is the Medical Board's understanding that this proposal would not have an adverse economic impact on the physicians or PAs who would be subjected to this requirement.

Cost Impact on Representative Private Person or Business

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

Effect on Housing Costs None

EFFECT ON SMALL BUSINESS

The Medical Board of California has determined that the proposed regulations or would not affect small businesses. The Board does not license businesses, the Board licenses individuals; therefore, there is no impact on small businesses or any business.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS

Impact on Jobs/Businesses

The Medical Board of California has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses, the elimination of jobs or existing businesses, or the expansion of businesses in the State of California.

Benefits of Regulation

The Medical Board of California has determined that this regulatory proposal will have the following benefits to health and welfare of California residents, worker safety, and the state's environment:

This proposal will update and clarify supervision requirements while a PA acts as a first or second assistant in surgery. Consumer protection is enhanced because physician supervision of PAs acting as first or second

assistants in surgery is precisely defined. This regulatory proposal benefits the health and welfare of California residents because it

represents the current standard of practice within the medical community and will enhance consumer protection by allowing better access to care while still protecting the consumer. This proposal would permit the physician to address other patient needs while authorized PA services are being performed. Under this proposal the physician is still responsible for supervising the PA and is required to be “immediately available” to the PA if needed at the request of the PA or to address any situation requiring the supervising physician’s services.

CONSIDERATION OF ALTERNATIVES

The Medical Board of California must determine that no reasonable alternative it considered to the regulation 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 proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Medical Board of California has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, any document incorporated by reference, the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request to the contact person named below, or by accessing the Board’s or the PA Board’s website.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the websites listed below.

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Glenn L. Mitchell, Jr., Executive Officer
Physician Assistant Board
Address: 2005 Evergreen Street, Suite 1100
Sacramento, CA 95815
Telephone No.: 916.561.8783
Fax No.: 916.263.2671
E-Mail Address: glenn.mitchell@mbc.ca.gov

The backup contact person is:

Name: Christine Valine
Medical Board of California
Address: 2005 Evergreen Street, Suite 1200
Sacramento, CA 95815
Telephone No.: 916.263.2389
Fax No.: 916.263.2387
E-Mail Address: regulations@mbc.ca.gov

Website Access: Materials regarding this proposal can be found at:

www.pac.ca.gov

or:

www.mbc.ca.gov

**MEDICAL BOARD OF CALIFORNIA
INITIAL STATEMENT OF REASONS**

Hearing Date: 7 February 2014

Subject Matter of Proposed Regulations: Supervision requirements: Physician Assistants acting as first for second assistants in surgery

Section Affected: 1399.541

Specific purpose of each adoption, amendment, or repeal

Problem being addressed

Physician Assistants (PA) are licensed health care practitioners that perform authorized medical services under the supervision of a licensed physician and surgeon (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, 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 (Business and Professions Code section 3509).

Existing law permits a PA to act as first or second assistant in surgery under the supervision of an approved supervising physician. In 2011, a concern was raised by a PA licensee to the Physician Assistant Board, that the current regulation at Section 1399.541 did not reflect current medical community standards when a PA acts as a first or second assistant in surgery. Additionally, the regulation was unclear regarding the degree of physician supervision of a PA acting as a first or second assistant in surgery.

Finally, the term, “approved supervising” physician as referenced in the current version of Section 1399.541(i)(2) needs to be removed as it is no longer accurate; legislation in 2002 eliminated the requirement that physicians who wish to supervise PAs be “approved” by the Medical Board of California. (Senate Bill 1981 (Stats. 1998, Chapter 736) repealed Business and Professions Code Section 3515.) After public discussion and deliberation, the PA Board relayed these concerns and a recommend proposal to the Medical Board for possible action.

To address the foregoing issues, the Medical Board proposes to amend Section 1399.541 to permit authorized medical services without the personal presence of the supervising physician if the supervising physician is immediately available to the PA. “Immediately available” would be defined as able to return to the patient, without delay, upon the request of the PA or to address any situation requiring the supervising physician’s services.

Anticipated benefits from this regulatory action

This proposal will amend the current regulation to update and clarify supervision requirements while a PA acts as a first or second assistant in surgery.

Consumer protection is assured because the term, “immediately available” is precisely defined and will ensure that the PA is appropriately supervised when acting as a first or second assistant in surgery. Additionally, amending the regulation will not reduce consumer protection because the supervising physician will be immediately available to provide assistance to the PA.

Factual Basis/Rationale

Under the existing regulation, a PA may act as a first or second assistant in surgery under the supervision of a supervising physician. To reflect current medical community standards, the proposal would clarify that a PA may so act without the personal presence of the supervising physician if the supervising physician is immediately available to the PA. “Immediately available” would be defined as able to return to the patient without delay, upon the request of the PA or to address any situation requiring the supervising physician’s services.

Over the course of numerous meetings from 2011 to 2013 for the Medical Board, Physician Assistant Board and Physician Assistant Committee, participants discussed the need to update the regulation and to specify the degree of supervision required for a PA when acting as a first or second assistant in surgery in light of the evolution of current medical practices for both professions.

Discussion originally focused on a legal opinion rendered in 2005 which interpreted Section 1399.541 to prohibit a PA from opening and closing surgical procedures on a patient under general anesthesia without the personal presence of a supervising physician and surgeon. However, at Physician Assistant Board and Committee meetings it was noted that the regulations have not been changed since 1991 and the 2005 legal interpretation was not consistent with the evolution of the practice. Conscious sedation did not exist when the regulations were first adopted. Further, the use of a PA in surgery has increased since 1991 and it was felt that PAs have proved to be capable of performing the requested procedures safely. Clarifying that the physician supervision would entail making the physician “immediately available” allows better access to care and still protects the consumer as the physician is still required to be “immediately available” to the PA and the patient. This proposal would allow the surgeon to leave the operating room to dictate the case, make phone calls, meet the next patient in surgery pre-op, and still make the physician immediately available to return to the operating room if needed. It was suggested that many surgery centers already operate in this manner when the physician is comfortable with the surgery team. Consequently, it was recommended to the Medical Board that the current regulation be amended to update it consistent with current practice.

A prior draft regulation to amend section 1399.541 was submitted to the Medical Board of California in May 2012, but the Medical Board had concerns about the breadth of the regulation and declined to take action. After considering the Medical Board's concerns, Physician Assistant Board staff started over and developed a different regulatory proposal.

In late July 2013, the Physician Assistant Board staff shared the new draft language with Medical Board of California staff and legal counsel to anticipate any concerns the Medical Board of California members may have. None were identified. At the August 2013 Physician Assistant Board meeting, board members voted to approve the proposed language and submit the proposal to the Medical Board of California for its consideration.

At their October 24, 2013 meeting, members of the Medical Board of California considered the proposed regulatory change and voted to direct staff to begin the rulemaking process to adopt the proposed regulatory changes.

At the meeting it was noted that the proposed language, which includes the term, "immediately available," is similar to Title 16, California Code of Regulations Section 1364.50 for physician supervision of other mid-level practitioners. Thus, with this proposal, the term, "immediately available" will be standardized, familiar, and understood by supervising physicians and PAs. This will eliminate PA and supervising physician confusion as to the definition of "immediately available."

This proposal would also make a non-substantive change to the text to strike the word "approved" as a modifier to the supervising physician to eliminate an inaccurate and outdated reference to past statutory requirements. Senate Bill 1981 (Stats. 1998, Chapter 736) repealed Business and Professions Code Section 3515. SB 1981 deleted the requirement that the Board review and approve applications for PA supervisors. Business and Professions Code Section 3515 was repealed by its own terms on January 1, 2002.

Underlying Data

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

1. Legal Opinion to Richard Wallinder, Executive Officer of the Physician Assistant Committee, dated April 25, 2005.
2. Meeting Minutes from the Physician Assistant Committee Meeting held May 19, 2011.
3. Meeting Minutes from Physician Assistant Committee Meeting held February 6, 2012.
4. Relevant Meeting Minutes from the Medical Board of California Meeting held May 3-4, 2012.

5. Meeting Minutes from Physician Assistant Committee Meeting held May 7, 2012.

Business Impact

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

The Medical Board regulates physicians and surgeons in the State of California and the Physician Assistant Board, within the jurisdiction of the Medical Board, regulates PAs. The Medical Board currently has approximately 128,641 licensees and the Physician Assistant Board has approximately 9,101 licensees for FY 2012-2013. PAs work in a variety of practice settings and specialties under the supervision of licensed physicians. The boards do not have data on either the number of physicians who supervise PAs by practice setting or the number of PAs who work as first or second assistants in surgery.

This regulation will clarify supervision requirements for PAs and supervising physicians as to the availability of the supervising physician when PAs are acting as first or second assistants in surgery. However, according to public comments received at board meetings, this proposed regulatory change represents the current evolution of the standard of practice within the medical community and, therefore, it is the Medical Board's understanding that this proposal would not have an adverse economic impact on the physicians or PAs who would be subjected to this requirement.

Economic Impact Assessment

This regulatory proposal will have the following effects:

- It will not create or eliminate jobs within the State of California because this proposed regulation represents the current evolution of the standard of practice within the medical community and will merely make conforming changes consistent with that practice by adding the term "immediately available" and an associated definition. As such, this proposal would not create or eliminate jobs within California.
- It will not create new business or eliminate existing businesses within the State of California because this proposed regulation represents the current standard of practice within the medical community, and will add the term, "immediately available" and, as such, would not create new business or eliminate existing businesses in California.
- It will not affect the expansion of businesses currently doing business within the State of California because this proposed regulation represents the current standard of practice within the medical community, and will merely make conforming changes consistent with that practice by adding the term, "immediately available" and, an associated definition. As such, this proposal would not affect the expansion of businesses currently doing business within California.

- This regulatory proposal benefits the health and welfare of California residents by allowing better access to care while protecting the consumer, as the physician is required to be “immediately available” to the PA and the patient.
- This regulatory proposal does not affect worker safety because this proposed regulation represents current standard of practice within the medical community and will add the term “immediately available.” It should not affect worker safety, as the physician is still responsible for supervising and making himself or herself “immediately available” to the PA and the patient.
- This regulatory proposal does not affect the state’s environment because the regulation reflects the current standard of practice within the medical community and seeks to clarify supervision requirements while a PA acts as a first or second assistant in surgery.

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:

- 1) Not adopt the regulation. This alternative was rejected because the current regulation does not reflect the current medical community standards and does not define or specify the degree of supervision required for a PA acting as a first or second assistant in surgery.
- 2) Adopt the regulation. Although alternative regulatory language was considered in 2012, the Medical Board determined that this alternative was the most feasible because it will ensure that the regulations reflect the current medical community standards with regard to PAs acting as first or second assistants in surgery, as well as adding and defining the term, “immediately available.” This language will eliminate PA and supervising physician confusion with regard to the degree of physician supervision required for safe practice.

**MEDICAL BOARD OF CALIFORNIA
SPECIFIC LANGUAGE OF PROPOSED CHANGES
MEDICAL SERVICES PERFORMABLE**

Amend Section 1399.541 of Article 4 of Division 13.8 as follows:

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

In any setting, including for example, any licensed health facility, out-patient settings, patients' residences, residential facilities, and hospices, as applicable, a physician assistant may, pursuant to a delegation and protocols where present:

(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.

(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 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)-(f), 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. Prior to delegating any such surgical procedures, the supervising physician shall review documentation which indicates that the physician assistant is trained to perform the surgical procedures. All other surgical procedures requiring other forms of anesthesia may be performed by a physician assistant only in the personal presence of an approved supervising physician.

(2) A physician assistant may also act as first or second assistant in surgery under the supervision of an ~~approved~~ 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 able to return to the patient, without delay, upon the request of the physician assistant or to address any situation requiring the supervising physician's services.

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