TITLE 16. Medical Board of California

NOTICE IS HEREBY GIVEN that the Medical Board of California (hereinafter referred to as the "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 the Sheraton Gateway Hotel and Marina, 1380 Harbor Island Drive, San Diego, CA 92101 at 9:05 a.m., on October 26, 2012. 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 Board at its office not later than 5:00 p.m. on October 15, 2012, or must be received at the hearing. The Board, 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: The Medical Board of California is authorized to adopt these regulations pursuant to Sections 2018 and 2023.5 (c), Business and Professions Code and to implement, interpret, and make specific Section 2023.5, Business and Professions Code. The Medical Board of California is considering adding a new Article to Division 13 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

A. Informative Digest

Adopt Section 1364.50 in Article 10, of Chapter 2, of Division 13, of Title 16 of the California Code of Regulations.

Physician availability is not addressed in current regulation.

SB 100 (Price, Chapter 645, Statutes of 2011) amended Section 2023.5 of the Business and Professions Code to add subdivision (c), which requires the Medical Board of California (Board) to adopt regulations on or before January 1, 2013 on the "appropriate level of physician availability needed within clinics or other settings using laser or intense pulse light devices for elective cosmetic procedures. However, these regulations shall not apply to laser or intense pulse light devices approved by federal Food and Drug Administration for over-the-counter use by a health care practitioner or by an unlicensed person on himself or herself".

B. Policy Statement Overview/Anticipated Benefits of Proposal

This regulation will clarify for physicians and mid-level practitioners how available the physician must be when the mid-level practitioner is performing elective cosmetic procedures using a laser or intense pulse light device.

This regulatory proposal benefits the health and welfare of California residents because it will set forth in regulations the current standard of care being used in clinics or other settings performing elective cosmetic procedures using lasers or intense pulse light devices, which will help to ensure that physicians meet these standards and are appropriately available to decrease the likelihood of patient harm.

C. Consistency and Compatibility with Existing State Regulations

__X__ The Medical Board of California has evaluated this regulatory proposal and it is not inconsistent nor incompatible with existing state 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:

__X__ The board 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.

AND

_____ The following studies/relevant data were relied upon in making the above determination: None

Cost Impact on Representative Private Person or Business:

The Medical Board of California is not aware of any cost impacts that 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 Board has determined that the proposed regulations would not affect small

businesses. This proposed regulation is reflective of the current standard of care being used in clinics or other settings performing elective cosmetic procedures using lasers or intense pulse light devices. As such, it should not affect small businesses within California.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/Businesses:

The Medical Board of California has determined that this regulatory proposal will not have

_____ a significant

____X____ any

impact on the creation of jobs or new businesses or 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 state's environment:

This regulation will clarify for physicians and mid-level practitioners how available the physician must be when the mid-level practitioner is performing elective cosmetic procedures using a laser or intense pulse light device. According to stakeholders, this regulation is reflective of the current standard of care and will help to ensure that physicians meet these standards and are appropriately available to decrease the likelihood of patient harm.

CONSIDERATION OF ALTERNATIVES

The Board 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, and any document incorporated by reference, and of 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 from the person designated in the Notice under Contact Person or by accessing the Board's web site:
http://www.mbc.ca.gov/laws/regulations_proposed.html

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 Board's Web site:
http://www.mbc.ca.gov/laws/regulations_proposed.html

CONTACT PERSON

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

Name:	Jennifer Simoes, Chief of Legislation 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

The backup contact person is:

Name:	Christine Valine Medical Board of California
Address:	2005 Evergreen Street, Suite 1200 Sacramento, CA 95815
Telephone No.:	(916) 263-2466
Fax No.:	(916) 263-2387
E-Mail Address:	chris.valine@mbc.ca.gov

Web site Access: Materials regarding this proposal can be found at http://www.mbc.ca.gov/laws/regulations_proposed.html.

MEDICAL BOARD OF CALIFORNIA
PHYSICIAN AVAILABILITY: ELECTIVE COSMETIC PROCEDURES
Specific Language of Proposed Changes

Add Section 1364.50 in Article 10, of Chapter 2, Division 13, of Title 16 of the California Code of Regulations to read as follows:

Article 10
Physician Availability

§1364.50. Physician Availability: Elective Cosmetic Procedures

Whenever an elective cosmetic procedure involving the use of a laser or intense pulse light device is performed by a licensed health care provider acting within the scope of his or her license, a physician with relevant training and expertise shall be immediately available to the provider. For the purposes of this section, "immediately available" means contactable by electronic or telephonic means without delay, interruptible, and able to furnish appropriate assistance and direction throughout the performance of the procedure and to inform the patient of provisions for post procedure care. Such provisions shall be contained in the licensed health care provider's standardized procedures or protocols.

NOTE: Authority cited: Sections 2018 and 2023.5 (c), Business and Professions Code.

Reference: Section 2023.5, Business and Professions Code.

MEDICAL BOARD OF CALIFORNIA

INITIAL STATEMENT OF REASONS

Hearing Date: October 26, 2012

Subject Matter of Proposed Regulations: Physician Availability: Elective Cosmetic Procedures

Section(s) Affected: Adopt Section 1364.50 in Article 10, of Chapter 2, Division 13, of Title 16.

Introduction

On October 9, 2011, Governor Jerry Brown signed SB 100 (Price, Chapter 645, Statutes of 2011). Among other provisions, this bill amended Section 2023.5 of the Business and Professions Code to add subdivision (c), which requires the Medical Board of California (Board) to adopt regulations on or before January 1, 2013 on the "appropriate level of physician availability needed within clinics or other settings using laser or intense pulse light devices for elective cosmetic procedures. However, these regulations shall not apply to laser or intense pulse light devices approved by federal Food and Drug Administration for over-the-counter use by a health care practitioner or by an unlicensed person on himself or herself".

Adopt Section 1364.50: This section meets the requirement in Business and Professions Code Section 2023.5 (c) and defines the physician availability needed within clinics or other settings using laser or intense pulse light devices for elective cosmetic procedures.

Factual Basis/Rationale

By statute, consumer protection is the Board's highest priority when exercising its regulatory function. As such, the Board held two interested parties meetings via the Board's Physician Supervisory Responsibilities Committee. The first meeting was on April 11, 2012 in Long Beach. The purpose of this meeting was to discuss the requirement in SB 100 to adopt regulations and the purpose of the discussion was to obtain professional and stakeholder input to assist Board staff in drafting regulatory language. The discussion was guided by a handout that included a decision tree of questions related to physician availability. After much discussion, there was a general consensus that a physician does not have to be physically present at all times when a laser or intense pulsed light (IPL) device is being used. There was also a general consensus that telehealth is an appropriate mode for being "immediately available" in many circumstances. Members of the Committee and stakeholders agreed that it would not be appropriate to specifically list procedures that require different levels of availability in the regulatory language and that geographic or chronologic limitations

should not be included in the regulatory language related to a physician's availability.

The second meeting was held on July 20, 2012 in Sacramento. The purpose of this meeting was to obtain professional and stakeholder input on four regulatory proposals drafted by staff. The four proposals consisted of the following: (1) a "community standard" proposal, which would require a physician to be available to the provider in accordance with the standards for the community in which the procedure is being performed; (2) an "on premises" proposal which would require a physician to be physically present on the premises where the procedure is being performed throughout the duration of the procedure; (3) a "physically present and immediately available" proposal, which would require a physician to be physically present, interruptible, and able to furnish assistance and direction throughout the performance of the procedure; and (4) a "not physically present but immediately available" proposal, which would require a physician to be immediately available and contactable by electronic or telephonic means without delay, interruptible, and able to furnish assistance and direction throughout the performance of the procedure.

It was the consensus of the committee and the stakeholders that the regulatory language include the language from Option 4 above, "not physically present but immediately available", and also ensure that the physicians supervising mid-level practitioners have relevant training and expertise to ensure consumer protection.

Underlying Data

Technical, theoretical or empirical studies, reports, or documents relied upon (if any): None

Business Impact

__X__ 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:
This regulation will simply clarify for physicians and mid-level practitioners how available the physician must be when the mid-level practitioner is performing elective cosmetic procedures using a laser or intense pulse light device. According to stakeholders, this regulation represents the current standard of care, as such, it should not have an adverse economic impact.

_____ This regulation may have a significant adverse economic impact on businesses. It might impact the following types of businesses:

_____

It would impose the following reporting, recordkeeping, or other compliance requirements: _____

_____

_____ Description of alternatives which would lessen any significant adverse impact on business (which includes small business):

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 standard of care being used in clinics or other settings performing elective cosmetic procedures using lasers or intense pulse light devices. As such, it should 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 care being used in clinics or other settings performing elective cosmetic procedures using lasers or intense pulse light devices. As such, it should not create new business or eliminate existing businesses within 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 care being used in clinics or other settings performing elective cosmetic procedures using lasers or intense pulse light devices. As such, it should not affect the expansion of businesses currently doing business within California.

- This regulatory proposal benefits the health and welfare of California residents because it will set forth in regulations the current standard of care being used in clinics or other settings performing elective cosmetic procedures using lasers or intense pulse light devices, which will help to ensure that physicians meet these standards and are appropriately available to decrease the likelihood of patient harm.

- This regulatory proposal does not affect worker safety because this proposed regulation represents the current standard of care being used in clinics or other settings performing elective cosmetic procedures using lasers or intense pulse light devices. As such, it should not affect worker safety, although it will better protect California consumers.

- This regulatory proposal does not affect the state's environment because this proposed regulation represents the current standard of care being used in clinics or other settings performing elective cosmetic procedures using lasers or intense pulse light devices. As such, it should not the state's environment.

Specific Technologies or Equipment

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

_____ This regulation mandates the use of specific technologies or equipment. Such mandates or prescriptive standards are required for the following reasons:

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. The Board is directed by statue to develop these regulations and there is, thus, no other method of defining the appropriate level of physician availability needed within clinics or other settings using laser or intense pulse light devices for elective cosmetic procedures.

California Medical Association
Physicians dedicated to the health of Californians
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October 9, 2012

Jennifer Simoes
Chief of Legislation
Medical Board of California
2005 Evergreen St, Suite 1200
Sacramento, CA 95815

Subject: Comment letter on Proposed Regulations: "Physician Availability: Elective Cosmetic Procedures"

Dear Ms. Simoes:

The California Medical Association (CMA) respectfully submits the following comments for consideration related to the proposed regulation which specifies the level of required physician availability for supervision of allied health professionals using laser or intense pulse light devices for elective cosmetic procedures. The comments are in response to the solicitation for comments in a notice of proposed rulemaking posted on August 7, 2012 containing proposed regulation §1364.5 (the "Proposed Regulations"). California Medical Association is an advocacy organization that represents more than 34,000 California physicians. Dedicated to the health of Californians, CMA is active in the legal, legislative, reimbursement and regulatory areas on behalf of California physicians and their patients.

I. Proposed Regulations

The proposed regulation clarifies for physicians and mid–level practitioners how available the physician must be when the mid–level practitioner is performing elective cosmetic procedures using a laser or intense pulse light device. The proposed regulations state:

"§1364.5. Whenever an elective cosmetic procedure involving the use of a laser or intense pulse light device is performed by a licensed health care provider acting within the scope of his or her license, a physician with relevant training and expertise shall be immediately available to the provider. For the purposes of this section, "immediately available" means contactable by electronic or telephonic means without delay, interruptible, and able to furnish appropriate assistance and direction throughout the performance of the procedure and inform the patient of provisions for post-procedure care, and such shall be contained in the standardized procedure or protocol."

II. CMA's Comments

Physician supervision is critical to ensuring quality patient care. Physicians represent the highest level of medical expertise and education. When delegating responsibilities to mid-level providers, high physician standards help to bring physician judgment and expertise to bear in a host of medical interactions. However, the breadth of medical specialties and health care settings require a degree of variability in supervision standards in order to remain relevant in a variety of circumstances and this is reflected in the legal standard for physician supervision of mid-level providers which allows for a great deal of variation in practice.

This need for flexibility is also demonstrated in the scope of practice of certain mid-level providers. For example, in California, a physician may only supervise four drug furnishing nurse practitioners at a time. Nurse practitioners do not have a clear statutorily defined scope of practice, although there are requirements for standardized protocols for these practitioners. Protocols must specify the drugs or devices that may be ordered, under what circumstances, the extent of supervision, and the method of periodic review. However, physicians exercise a great deal of autonomy in determining the level of use for these practitioners and the degree of physician involvement in various procedures through protocols.[1]

As a result of different requirements for different providers, developing a standard for physician supervision quickly becomes a very complicated matter that requires balancing a number of interests.

CMA supports the proposed regulations and believes that the language adequately specifies a level of physician supervision that protects patients undergoing elective cosmetic laser procedures performed by allied health professionals. CMA supports a sliding scale of supervision based on the complexity of the procedure being performed.

The proposed regulations recognize that is not always feasible or necessary for a physician to be on site when supervising mid-level practitioners. However, the regulations do not prevent individual physicians from implementing a higher standard of supervision (ex. direct on-site supervision of allied health professionals) when necessary.

We urge the Medical Board of California to approve the proposed regulations.

Sincerely,

Yvonne Choong
Associate Director, Center for Medical and Regulatory Policy
California Medical Association

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[1] This 4-to-1 ratio is the same for drug furnishing certified nurse midwives. [B&P Code 2836.1 (d), 2746.51 (a)(4)] Additionally, a physician may only supervise four physician assistants (PA) at a time irrespective of whether they are furnishing medications. [B&P Code 3516 (b)] And in relation to certified nurse anesthetists, Medicare rules require that a physician supervise no more than four anesthesia procedures concurrently. [42 C.F.R. §415.110].

ARTICLE 10

PHYSICIAN AVAILABILITY

#1364.50. Physician Availability: Elective Cosmetic Procedures

I do not agree with the section regarding "immediately available" by e-mail or telephone. A licensed physician should be doing invasive laser and intense pulse light procedures, not a registered nurse. I was severely burned on my face by a laser procedure done by an R.N. at a "med-spa". A doctor was not informed and was miles away from the establishment. My face and neck actually had the laser machine burns in horizontal streaks across my cheeks and neck. I was devastated and would not go out of the house for a month. For years I have had to use many cosmetic products to cover the scars. It also had a physical and mental effect on me and my family. I found out later that this spa had also burned many other patients and some much more severely. The spa only offered me "calming treatments" with their esthetician. I was not given an appointment with their covering physician until 3 months later (and she was a proctologist). She only recommended I continue to go to their spa for treatments to rectify their mistakes. After 7 months their doctor said they could not help me anymore.

Immediately after I was burned I went to our physician and a dermatologist. My physician told me that because of my age, the scars might never go away completely and the dermatologist said it would take thousands of dollars to repair the damage.

These are the reasons I do not agree with the wording of "immediately available by e-mail or telephone". Think it should read "will be seen by the spa's physician within hours and the same day" if the procedures are just being done by a licensed health care provider and not a Board Certified Physician.

Carmella Takacs

Concord, California