



# MEDICAL BOARD OF CALIFORNIA

## Executive Office



### MEMORANDUM

<b>DATE</b>	July 6, 2012
<b>TO</b>	Members, Committee on Physician Supervisory Responsibilities
<b>FROM</b>	Jennifer Simoes Chief of Legislation
<b>SUBJECT</b>	<b>Proposed Physician Availability Regulations</b>

Members, this memo provides information regarding proposed regulations relating to the availability of a licensed physician when lasers or intense pulse light devices are used to perform elective cosmetic procedures. As you may recall, the Committee on Physician Supervisory Responsibilities (Committee) met in Long Beach earlier this year and had a robust and animated discussion about the availability of physicians when elective cosmetic procedures using laser or intense pulse light devices are performed.

#### BACKGROUND

By way of background, subdivision (c) of section 2023.5 of the Business and Professions Code provides:

"(c) On or before January 1, 2013, the board shall adopt regulations regarding 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 the federal Food and Drug Administration for over-the-counter use by a health care practitioner or by an unlicensed person on himself or herself." (Emphasis added.)

The purpose of regulations is to implement, interpret or make specific laws enforced and administered by state agencies. (See Gov. Code, § 11342.600.) Regulations have to meet certain standards to be approved by the Office of Administrative Law, and those standards are: necessity, authority, clarity, consistency, reference, and non-duplication. When exercising its regulatory function, protection of the public shall be the highest priority of the Medical Board of California (Board). (See Bus. & Prof. Code, § 2001.1.)

With that backdrop in mind, let's turn to four regulatory proposals to implement the provisions of section 2023.5 that the Committee may wish to consider. Please note the January 1, 2013 deadline for adopting regulations on this subject. It is anticipated that the Committee will select a proposal and recommend to the Board that the selected proposal be set for a regulatory hearing. Such action will be necessary if the January 1, 2013, deadline is to be met.

## REGULATORY PROPOSALS

1) *Community Standard Proposal*. "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 shall be available to the provider in accordance with the standards for the community in which the procedure is being performed."

Please note that this proposal may not be consistent with the clarity standard as it would vary depending on the location. Additionally, the standard of care in a disciplinary proceeding must be established by an expert. A physician who consults the regulations for guidance would not necessarily derive the needed information; he or she would need to go further.

2) *On Premises*. "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 shall be physically present on the premises where the procedure is being performed throughout the duration of the procedure."

This is a location based requirement. Please note that the physician could be involved with other patients or otherwise engaged but yet still on the premises. The concern with this standard is that it may be too restrictive as certain health care professionals working within their scope of practice under standardized procedures or delegation agreements would not require a physician on the premises.

3) *Physically Present and Immediately Available*. "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 shall be immediately available to the provider. For the purposes of this section, "immediately available" means physically present, interruptible, and able to furnish assistance and direction throughout the performance of the procedure but without reference to any particular physical boundary."

This proposal is similar to the federal Centers for Medicaid Services regulation but that rule is not specifically aimed at elective cosmetic procedures. The Committee, when considering this proposal or proposal 2, may wish to further define the term "premises" as there may be some uncertainty as to whether "premises" means room, suite, office, complex, or other area. Again, the concern is that this standard may be too restrictive as certain health care professionals working within their scope of practice under standardized procedures or delegation agreements would not require a physician on the premises.

4) *Not Physically Present but Immediately Available.* "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 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 assistance and direction throughout the performance of the procedure but without reference to any particular physical boundary."

This proposal allows the physician to be remote from the location from which the procedure is performed.

As mentioned above, whenever the Board exercises its regulatory function, protection of the public is its highest priority. The Committee may wish to revise or amend these proposals.

#### **RECOMMENDATION**

Staff recommends that the Committee focus their discussion on either option 1, the community standard proposal, or option 4, the not physically present but immediately available proposal, or possibly discuss a hybrid option that combines option 1 and 4. These options seem to be most in line with the discussion at the previous committee meeting that included input from committee members. Once a decision is made, the regulatory proposal agreed upon by the Committee will need to be presented to the full Board for review, approval, and to set it for regulatory hearing.