#### MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: January 17, 2014

ATTENTION: Members of the Committee on Physician Supervisory

Responsibilities

SUBJECT: Medical Spas

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This memo provides background information for a discussion by this Committee on medical spas.

### **MEDICAL SPAS - STAFF RECOMMENDATION:**

A medical spa is not a facility that is currently licensed and regulated in California. However, as explained in the background of this memo (below), licensed physicians and other health care providers are licensed and regulated in California. The purpose of defining a medical spa in law would be to license and regulate this type of facility. Staff does not recommend creating a definition for medical spas in law, as any individual providing medical services is required to be licensed and regulated accordingly. If an individual is providing a service that requires a license or is outside their scope of practice in any type of facility (including a medical spa), this is already a violation of law, which can be pursued criminally or administratively.

#### **BACKGROUND:**

The International Medical Spa Association defines a medical spa as follows:

"A medical spa is a facility that operates under the full-time, on-site supervision of a licensed health care professional. The facility operates within the scope of practice of its staff, and offers traditional, complementary, and alternative health practices and treatments in a spa-like setting. Practitioners working within a medical spa will be governed by their appropriate licensing board, if licensure is required."

Currently, the Medical Board of California (Board) has information on its website related to medical spas and cosmetic procedures, as this is not a new issue for the Board.

### Medical Spa Information Currently Available on the Board's Website for Consumers:

Medical treatments should be performed by medical professionals only. There is risk to any procedure, however minor, and consumers should be aware of those risks. While it is illegal for unlicensed personnel to provide these types of treatments, consumers should be aware that some persons and firms are operating illegally. Cosmetologists or estheticians, while licensed professionals and highly qualified in superficial treatments such as facials and microdermabrasion, may never inject the skin, use lasers, or perform medical-level dermabrasion or skin peels. Those types of treatments must be performed by qualified medical personnel. In California, that means a physician, or a registered nurse or physician assistant under the supervision of a physician.

Patients must know the qualifications of persons to whom they are entrusting their health. Those seeking cosmetic procedures should know that the person performing them is medically qualified and experienced. Specifically, patients should:

• Know who will perform the procedure and his or her licensing status: If a physician is performing the treatment, the patient should ask about the physician's qualifications. Is the physician a specialist in these procedures? Is he or she board certified in an appropriate

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- specialty? Licensing status may be verified on the Board's website at www.mbc.ca.gov., "Check Your Doctor." Board certification status may be verified at <a href="https://www.abms.org">www.abms.org</a>.
- If a registered nurse or physician assistant will be doing the procedure, what are his or her qualifications? Where is the physician who is supervising them? Are they really being supervised, or are they acting alone with a paper-only supervisor? (Although the physician does not have to be onsite, he or she must be immediately reachable.) Again, the patient should check the supervising physician's credentials, as well as the nurse or physician assistant. Those websites are www.rn.ca.gov and <a href="https://www.pac.ca.gov">www.pac.ca.gov</a>.
- Be fully informed about the risks: All procedures carry risks, and conscientious
  practitioners will fully disclose them. Medical professionals have an ethical responsibility
  to be realistic with their patients and tell them what they need to know. Use caution if
  procedures are being heavily marketed, with high-pressure sales techniques promising
  unrealistic results.
- Observe the facility and its personnel: Medical procedures should be done in a clean environment. While one cannot see germs, one can see if the facility looks clean and personnel wash their hands, use gloves, and use sound hygienic practices.
- Ask about complications, and who is available to handle them: If the patient has an adverse reaction, he or she should know who will be there to help. Who should the patient call, and what hospital or facility is available where the physician can see the patient? Qualified physicians have facilities or privileges at a hospital where they can handle emergencies.
- Don't be swayed by advertisements and promises of low prices: There are a host of medical professionals offering competent, safe cosmetic procedures. If they are being offered at extremely low prices, there is a good possibility that what they are advertising is not what will be delivered. There have been tragic cases of unscrupulous practitioners injecting industrial silicone and toxic counterfeit drugs that have made patients critically ill, caused disfigurement, or resulted in death.
- Know that there is a substantial financial cost to obtaining qualified treatments, as well as some risk. If the patient wants the best results, he or she should do his or her homework and only trust those who demonstrate competence and caution.

#### **Cosmetic Procedure Information Currently on the Board's Website:**

In 2006, Senator Liz Figueroa authored legislation (SB 1423, Chap 873) that directed the medical and nursing boards to work together to study the issue of safety in the use of lasers in cosmetic procedures. Both boards held public forums on the subject. What was learned in these forums is that the current law is being violated with impunity by many in the cosmetic medical field.

The current environment gives rise to violations of the laws governing the business of medical practices, including violations of the corporate practice prohibitions, as well as fee-splitting and payment for referrals. The illegal business models give rise to the use of unlicensed or inappropriately licensed personnel, paper-only supervision ("rent-a-license") of allied health professionals, consumer confusion over the medical nature of the procedures, and confusion over who is responsible for the patient. Patients are not fully informed of the risks and often do not know the medical nature of the treatments or who is responsible for their care.

The use of prescriptive medical devices and injections for cosmetic reasons is the practice of medicine and the same laws and regulations apply to these types of treatments as those driven by

medical necessity. There are no separate laws governing these procedures, and physicians will be held to the same standard as they are for their routine medical practices. This means that the standards for informed consent, delegation to allied health professionals, physician-patient confidentiality and boundaries, maintaining medical records, as well as responsibility and liability apply to physicians, even those denominated "medical director."

# Physician responsibility when delegating procedures to allied health professionals:

In the practice of medicine, physicians routinely delegate functions to allied health professionals. Physicians, however, may only delegate to appropriately licensed staff that they know to be capable of performing the task. Lasers and other prescriptive devices and prescriptive drugs must only be utilized by licensed registered nurses, nurse practitioners, or physician assistants. No unlicensed staff, including medical assistants, may use these devices or drugs, regardless of the level of training or supervision. Likewise, delegation to improperly licensed personnel, such as cosmetologists or estheticians, is prohibited.

# Supervision of those to whom procedures are being delegated:

While current law allows the delegation of laser treatments and injections to the above mentioned licensees, the law requires supervision by the physician. In the current environment, many have operated under the opinion that since the nursing regulations are broadly written, nurses may perform anything anywhere with essentially no supervision as long as there are "standardized procedures" or "delegation of services" documents on file.

Section 2023.5 was signed into law and added to the Business and Professions Code in 2011, and required the Board to adopt regulations 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." These regulations were adopted and became effective on July 1, 2013. The regulatory language states:

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 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.

### Nurses:

Standardized procedures for nurses allow nurses to perform procedures while the physician is not on-site; however, they do not absolve physicians of their supervision responsibilities. Nor does the law allow nurses to set up a practice in a salon, hire a physician supervisor, or perform medical procedures independently.

The law does not contain a legal definition of supervision, and therefore, absent a legal definition, the plain English definition applies. "Supervision" is defined as the act of supervising, which is to

oversee, to direct, to have charge, to inspect, to provide guidance and evaluation. The law and regulations support this definition.

As an example, the regulations for "standardized procedures guidelines" require physicians to be responsible for ensuring the experience, training, and education requirements for performance of the delegated function – and this must be documented. The regulations require that a method of initial and continuing evaluation of the nurses' competence be established. Further, it is the responsibility of the physician to examine the patient before delegating a task to a registered nurse.

An appropriate prior examination is required where prescriptive drugs and devices will be used, and this examination may not be delegated to registered nurses. After performing the examination, the supervising physician may delegate a procedure that utilizes a prescriptive device to a nurse working under standardized procedures.

The guidelines further require the standardized procedures to describe the circumstances under "which the registered nurse is to immediately communicate with a patient's physician concerning the patient's condition." While there is no actual mileage limit relating to supervision, this requirement certainly means that the physician must be immediately reachable and able to provide guidance in the event of an emergency or the need for a higher level of care that must be provided by the physician. Physicians must be within a geographical distance that enables them to effectively provide supervision and support when needed or upon request.

For more specific information on registered nurse and nurse practitioner regulations, the Board of Registered Nursing website is: <a href="www.rn.ca.gov">www.rn.ca.gov</a>.

#### Nurse Practitioners:

Nurse practitioners are granted much more autonomy than registered nurses. They are advanced practice nurses who are master's-level educated, and, for that reason, may perform certain functions with a different level of supervision than registered nurses. The major exception to the rules governing their supervision in cosmetic procedures is that they may be delegated the task of providing the appropriate prior examination and ordering the drug or prescriptive device for the patient, if acting under standardized procedures.

### Physician Assistants:

The supervision of physician assistants (PAs) is similar to that of nurses; however, the regulations governing PAs are much more specific. First, PAs may only be delegated tasks that are part of the physician's customary practice. In other words, obstetricians may supervise PAs treating obstetrical patients, pediatricians may supervise PAs providing care to pediatric patients, etc. Therefore, if cosmetic medicine is not a part of the physician's customary practice, the physician may not supervise a PA providing cosmetic procedures. In addition, physicians may only supervise four PAs at any given time, and must be in the facility with the PA or be immediately available by electronic communication if the PA is working under a delegation of services agreement.

PAs may be delegated the "appropriate prior examination" of the patient, but there are methods enumerated in the law and regulations on how physicians must provide their supervision and

evaluation. For more specific information, all of the rules and regulations are available at the Physician Assistant Board website: www.pac.ca.gov.

#### Qualifications of Physician Supervisors:

Physicians may only delegate to those that they know to be capable of performing the task. If they are to supervise the procedure, the physician too should be capable of performing it. One cannot provide guidance, direction, evaluation and oversight unless one is knowledgeable and competent in the procedure being delegated.

The law does not require board certification to perform cosmetic procedures. That said, however, one should not think that the absence of this requirement allows anyone of any specialty to supervise cosmetic procedures, unless the physician has sufficient knowledge and training in the procedures being performed.

### Business arrangements; issues of ownership and control:

California law prohibits the corporate practice of medicine. Laypersons or lay entities may not own any part of a medical practice (Business and Professions Code Section 2400). Physicians must either own the practice, or must be employed or contracted by a physician-owned practice or a medical corporation. (The majority of stock in a medical corporation must be owned by California licensed physicians, with no more than 49% owned by other licensed healthcare professionals, such as nurses, physician assistants, nurse practitioners, etc. No stock in a medical corporation may be owned by a lay-person (Corporation Code Section 13401.5(a)).

Businesses that provide management services, franchises or other models that result in any unlicensed person or entity influencing or making medical decisions are in violation of the law. Management Service Organizations (MSOs) arranging for advertising, or providing medical services rather than only providing administrative staff and services for a physician's medical practice (non-physician exercising controls over a physician's medical practice, even where physicians own and operate the business), are also engaging in illegal conduct. Also, many current business arrangements violate the prohibition against fee-splitting or giving any consideration for patient referrals. The current practice of lay-owned businesses hiring medical directors is also prohibited. A physician who acts as medical director of a lay-owned business is aiding and abetting the unlicensed practice of medicine. (See Precedential Decision No. MBC – 2007-01-Q, in the matter of the Accusation against Joseph F. Basile.) Physicians who become employees or contractors of lay-owned spas and therefore violate the laws may be disciplined for unprofessional conduct.

## Physician responsibility for back-up systems and emergency plans:

Physicians who perform or delegate treatments are responsible for their patients' care. As supervisors, they are responsible to ensure that back-up systems and emergency plans are in place. Under current law, the patients are the physician's responsibility, and the physician is responsible for treating mishaps, complications or any other emergency that might arise from the treatments the physician has delegated. While nurses are responsible for their patients within their scope-of-practice, according to the Medical Practice Act physicians have the ultimate responsibility for the care of their patients.

### Physician responsibility for patient informed consent and education:

All medical procedures must be preceded by informed consent, which should include the possible risks associated with the treatment. While there is no specific code section that enumerates the contents of an informed consent, the well-established doctrine of informed consent in case law requires that patients must be, at a minimum, informed of:

- The nature of the treatment;
- The risks, complications, and expected benefits, including its likelihood of success; and
- Any alternative to the recommended treatment, including the alternative of no treatment, and its risks and benefits.

Providing sufficient information to constitute informed consent is the responsibility of the physician.

# Physician responsibility for advertising and marketing:

California law requires advertising to include the physician's name or the name for which they have a fictitious name permit (Business and Professions Code Section 2272). While nurses may be performing the treatment, the name of the supervising physician, or his or her registered fictitious name, must be in the advertisement.

The law governing physician advertising is specific, and requires the physician advertisements not be misleading. California law is very specific in prohibiting many of the advertising practices being used to promote cosmetic treatments. The use of models, without stating that they are models, the use of touched-up or refined photos, and claiming superiority of the facility or procedures with no objective scientific evidence is prohibited. Also, the use of discount or "bait and switch" promotions is prohibited. The use of "for as low as" in advertising procedures, is strictly prohibited. The laws relating to physician advertising, Business and Professions Code Section 651, may be viewed on the Board's website: www.mbc.ca.gov.