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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	92044697
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**The Bottom Line:
The Business of Medicine – Medical Spas**

There has been an explosion of cosmetic medicine over the past few years, and many physicians are being approached to "increase their bottom line" by entering into this lucrative field. Recently, our office received a letter from a business promoting the many programs they offered to physicians that contained the following message:

"... Lastly, we are very excited to announce our Medical Director program. This opportunity allows Doctors and Physicians to earn up to \$400 per month per spa in their area. We have several DaySpas that anxiously await a Medical Director and we would anticipate a large number of client referrals to your practice.'.....'We would be happy to discuss how they can benefit your practice and grow your bottom line.'"

This business is offering the opportunity for physicians, for a fee, to rent their license to a business so that the business may engage in the practice of medicine --- a profession for which it has no license or qualifications.

Is what this business proposes legal? Can physicians simply sign-on, lend their names on paper to a salon or spa, collect "up to" \$400 a month, and escape any liability or responsibility for the patients treated by the business? NO!

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. Over the past year, the boards have been holding public forums on the subject. What we have learned 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:

There is a tendency for the public, and some in the profession, to view laser treatments, Botox and cosmetic filler injections as cosmetic rather than medical treatments. The use of prescriptive drugs and devices, however, 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 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.

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.

When functioning under "standardized procedures," physicians need not be present in the facility when the procedures are being performed. The facility, however, must be a medical setting. Regulations require that the location be an "organized healthcare system," which is not a salon, spa, or other facility not under the control of the physician.

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: www.rn.ca.gov.

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, and so forth. 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 Committee website: www.pac.ca.gov.

Supervision of all allied health professionals:

"Supervise" is a verb, and it requires those calling themselves supervisors to guide, direct, oversee, and evaluate performance. Physicians must really supervise, not simply lend their license to allied health professionals on paper without providing any supervision. A "supervising" physician who does not give direction, oversee or inspect, is not performing the task of supervising and is in violation of the law.