

Medical Board of California

January 26, 2010

TO: Members,
Physician Supervision Advisory Committee

*Rec'd 1/17/2010
[Signature]*

FROM: Janie Cordray,
Research Director

*N. Ca. Cosmetic
Nurs. Assoc
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SUBJECT: Historical Perspective of Medical Board Activities Relating to Physician Supervision and Cosmetic Medicine Practice

In order to assist the Committee with its discussions, staff thought it would be helpful to provide an overview of the laws and regulations relating to physician supervision, especially as they relate to cosmetic practices.

How Did We Get Here?

The most recent work by the Board on the issues surrounding physician supervision was as a result of legislation passed in 2006. SB 1423 (Figueroa; Chap 873, Stats. of 2006) added section 2023.5 to the Business & Professions Code, directing the Medical Board and the Board of Registered Nursing to jointly review the issues of the safety of lasers in elective cosmetic procedures. Section 2023.5 states:

(a) The board, in conjunction with Board of Registered Nursing, and in consultation with the Physician Assistant Committee and professionals in the field, shall review issues and problems surrounding the use of laser or intense light pulse devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants. The review shall include, but need not be limited to, all of the following:

- (1) The appropriate level of physician supervision needed.*
- (2) The appropriate level of training to ensure competency.*
- (3) Guidelines for standardized procedures and protocols that address, at minimum, all of the following:*
 - (A) Patient selection.*
 - (B) Patient education, instruction, and informed consent.*
 - (C) Use of topical agents.*

(D) Procedures to be followed in the event of complications or side effects from the treatment.

(E) Procedures governing emergency and urgent care situations.

(b) On or before January 1, 2009, the board and the Board of Registered Nursing shall promulgate regulations to implement changes determined to be necessary with regard to the use of laser or intense pulse light devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants.

While this law is specific to lasers and IPLs, the legalities surrounding those treatments are fully relevant and applicable to all other medical practices, including other medical device use and administration of injectables.

Review of Issues – Information Gathered at Public Forums:

In 2007, to conduct the review of issues mandated by the law, the Medical and Nursing Boards held three public forums to solicit comment on the safety of laser use in cosmetic procedures.

As a result of the forums, held in Santa Ana, Sacramento, and San Diego, Board members and staff heard from a number of interested parties. Those who made formal presentations were:

- American Academy of Cosmetic Surgeons
- American Association of Medical Esthetic Nurses
- American Laser Centers
- American Society of Cosmetic Dermatology & Aesthetic Surgery
- California Academy of Cosmetic Surgeons
- California Academy of Facial Plastic and Reconstructive Surgeons
- California Academy of Physician Assistants
- California Association of Nurse Practitioners
- California Nursing Association
- American Society of Dermatological Surgery
- California Society for Dermatological Surgery
- California Society of Dermatologists
- California Society of Plastic Surgeons
- Norm Davis, J.D., Healthcare attorney
- Christine Lee, M.D., Dermatologist
- Lumier Medical, Inc.

- Stephen Moore, Patient Advocate
- Alan Voss, A. L. Voss, Associates, Medical Device Consultant

In addition to the formal presentations made by these individuals and organizations, a number of persons offered comment, including individual nurses, physicians, physician assistants, and consumers.

In preparation for the Forums, Medical Board and Nursing Board staff met to discuss the issues relating to the environment of cosmetic laser practice. Staff noted that laser practice was often not safe or legal, and, specifically, had observed the following problems:

- Ownership violations of "Medical Spas" or combined cosmetic & medical practices;
- Corporate practice violations: the employment of a "Medical Director," "Collaborative Physician" or "Supervising Physician";
- Fee-splitting, paying for referrals, and a number of business schemes designed to circumvent the prohibition of hiring physicians;
- Remote or absent supervision;
- Use of non-licensed, or inappropriately licensed personnel;
- Consumer confusion as to the medical nature of laser procedures and issues of liability;
- Potential for patient harm.

The presentations made by the various professional associations at the Forums echoed the above. Testimony demonstrated that there is frequent disregard of the law in the treatment of patients. In addition to highlighting the problems of the industry, there were a number of recommendations voiced by those offering testimony. Those offering testimony relating to physician supervision issues suggested the following:

- Increase the definition of medical practice and medical offices or settings;
- Better define the span of control over sites, and possibly limit the number of persons supervised;
- Increase supervision of RNs, requiring the same for RN's standardized procedures as for physician assistants;
- Close any loopholes in the standardized procedure guidelines of nurses;
- Require that the supervising physician be on-site, or available via telecommunications at all times during the procedures;

- Allow delegation of tasks or procedures only consistent with the supervising physicians' specialty or "usual or customary practice";
- Require physician supervisors to review and examine the nurse's performance;
- Require physicians do a skin exam before any laser treatments;
- Only allow laser treatments in medical settings, and;
- Enforce the current laws and regulations.

What was most interesting about the testimony provided was that most of the suggestions were already addressed in law or regulation. The very practices which were most complained about were often already a violation of law! The problems appeared to be a lack of enforcement, not a lack of laws or regulations. (A memo entitled "Current Laws and Regulations Relating to the Use of Lasers and Their Enforcement" is attached, and provides a complete overview of the relevant laws and regulations.)

In 2008, the Medical Board members were presented the information gathered at the Forums. Staff made the following recommendations:

- Publish a statement clearly outlining the current law and the responsibilities of physicians in providing laser treatments. An article, entitled "The Bottom Line," was approved by the members for publication. (The final version of the article is attached. It was published in the Board's Newsletter and is posted on the Board's website.)
- Re-write and distribute "Medical Spa – What You Need to Know," an article for consumers. (The article was approved and it has been published and distributed.)
- Support the reestablishment of "Operation Safe Medicine" which, in addition to addressing unlicensed practice, would work to enforce the laws relating to cosmetic procedures. (The OSM was reestablished, and began work in July 2009.)
- Work with the Nursing Board to develop an enhanced communication system in cases involving physicians and nurses;
- Utilize the citation and fine process to deter further violations; and
- Before January 1, 2009, report to the Legislature on the Board's actions and intentions.

All of the above recommendations were adopted by the Board, and all have been acted upon.

The Legislature's and Associations' Response; Unsuccessful Legislation

In 2008 and 2009, a number of bills were introduced relating to cosmetic surgery and medical spas. Most were not successful.

AB 2398 (Nakanishi; 2008): This bill was sponsored by the American Society for Dermatological Surgery, and sought to improve patient safety by making it tougher for corporate entities to practice medicine illegally in California. (This practice is illegal under current law, but it is often difficult to prove that physicians “knowingly” broke the law.) It would have authorized the revocation of the license of a physician who practices medicine with a business organization that offers to provide, or provides, outpatient elective cosmetic procedures, knowing that it is owned or operated in violation of the prohibition against the corporate practice of medicine. This bill failed to reach the floor.

AB 252 (Carter; 2009): Initially, this bill was essentially a reintroduction of the 2008 Nakanishi bill (AB 2398). Again, this bill was sponsored by the American Society for Dermatological Surgery, and addressed violations of the corporate practice of medicine in the cosmetic medicine industry. It specified that non-physician entities owning cosmetic medicine practices providing medical treatments (laser hair removal, laser resurfacing, Botox and filler injections) were in violation of the corporate practice prohibition of B&P Code Section 2400. This bill would have made a violation of the corporate practice bar a felony for the artificial (non-medically owned) entities, and grounds for license revocation for physicians who knowingly worked or contracted with these entities. While this bill was successful in the Legislature, it was vetoed by the Governor.

SB 674 (Negrete McLeod; 2009): Covered a variety of subjects, including advertising, outpatient setting accreditation, the wearing of name tags, and public information. The most relevant to the Committee's discussions is the portion of the bill that addressed the supervision of laser and IPL device procedures. Specifically, it would have required the Board to adopt regulations regarding the appropriate level of physician availability for facilities using lasers or IPLs. While this bill was identified as an “author sponsored” bill, it was supported by the American Society of Dermatologic Surgery, the California Society of Dermatology and Dermatologic Surgery, the California Medical Association, and the California Society of Plastic Surgeons. Again, this bill was successful in the Legislature, but was vetoed by the Governor.



Why Are We Here?

While SB 674 (Negrete McLeod) was vetoed, under its current authority, the Board may examine the issues surrounding physician supervision and physicians' availability to those supervised. The Medical Board has regulatory authority over physicians, while the Nursing Board has regulatory authority over nurses. For that reason, this Committee will need to focus on physician responsibility.

Following the vetoing of SB 674, its author, Senator Negrete McLeod wrote to the Board. She asked that the Board consider conducting a review of the issues surrounding physician supervision and availability. She noted that no legislation was needed for the Board to conduct such a review. This Advisory Committee is partially a response to the Senator's request.

What Can We Expect?

If the past is a predictor of the future, the Advisory Committee can expect to hear from the same parties as those providing testimony at previous Board meetings and the BRN/MBC Public Forums on Laser Safety.

If the past is a predictor of the future, legislation introduced can expect to be supported and opposed by the same interest groups.

If previous successful actions by the Board are predictors of future achievements, then there is a reasonable expectation for success if the Committee and Boards' activities and actions:

- focus upon issues under the Board's jurisdiction;
- focus upon issues relating to public protection, and;
- resist turf battles and issues of economic interests.

The Board has enjoyed a number of successes using the above principles, especially as they relate to cosmetic procedures. The Board has sponsored legislation and promulgated regulations addressing board certification, outpatient surgery settings, advertising, and liposuction, among others. The Board has prevailed despite the considerable controversy surrounding these issues. The common denominator among these activities was a willingness to focus on matters within the Board's jurisdiction relating to public protection.

The Board has every interest and authority to set standards for its physicians under current law. That said, however, if current law is not sufficient, then future legislation will be needed. If, however, authority and jurisdiction of the Board already exists to address public protection deficiencies, then it is possible (and often preferable) to utilize its authority through greater enforcement or promulgation of regulations. Neither action would require legislative action.

I will be at the meeting on January 28, and available to answer the members' questions. If, in the meantime, however, you have any questions or suggestions, feel free to contact me at 916-263-2389, or by e-mail at jcordray@mbc.ca.gov.

Attachments:

- Memorandum: Current Laws and Regulations Relating to the Use of Lasers and Their Enforcement
- Article: The Bottom Line, The Business of Medicine – Medical Spas (written for physicians)
- Article: Medical Spas (written for consumers)

Medical Board of California

January 7, 2008

TO: Members,
Medical Board of California

FROM: Janie Cordray,
Research Director

SUBJECT: **Current Laws and Regulations Relating to the Use of Lasers and Their Enforcement**

Background

SB 1423 (Figueroa; Chap 873, Stats. of 2006) added section 2023.5 to the Business & Professions Code, which directs the Medical Board and Board of Registered Nursing to review the issues of the safety of lasers in elective cosmetic procedures. To gather information on this subject, the Boards held three joint forums to solicit testimony from providers and users of this technology.

As more fully explained in the previous memo, entitled "SB 1423; Medical Board's Responsibility to Review Laser Safety in Elective Cosmetic Procedures; Report on Laser Forums," there is often disregard for the current law and regulations. The forums yielded testimony from patients and the profession on how some current practice environments often violate the law and endanger patients.

In summary, there has been a tremendous increase in cosmetic procedures, and the treatments are often performed in non-traditional, non-medical settings. The current environment can give rise to violations of the laws governing the business models and ownership of medical practices, including violations of the corporate practice bar, as well as fee-splitting and payment for referrals. The illegal business models may give rise to the use of non-licensed 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 may not be fully informed of the risks and often do not know the medical nature of the treatments or who is responsible for their care.

The profession may not be well informed either. In some cases, physicians are approached by companies that solicit their involvement in business schemes that are not consistent with existing law. A specific example is a corporation soliciting physicians to essentially rent their license to medical spas for \$400 per month, per site, with no real involvement or real supervision of nursing personnel, by acting as a "medical director."

In addition, physicians are being asked to participate in a business management that may be legal on paper, but in reality are in violation of the responsibility of physicians operating medical practices.

Ironically, some of those making presentations or testifying at the forums essentially admitted to being part of a practice that violated one or several California laws.

Discussion of Current Statutes and Regulations and Current Enforcement as they Relate to Physicians

As more fully explained in the previous memorandum (SB 1423; Medical Board's Responsibility to Review Laser Safety in Elective Cosmetic Procedures; Report on Laser Forum") those testifying at the forums voiced a number of concerns and recommended changes or additions in law, as well as enforcement actions. The majority of recommendations made by those in attendance at the Forums relate to legal requirements already addressed by existing statute and regulations.

Current Law & Regulations

It is important to note that while the law requires the Medical and Nursing Boards to jointly study the issues and consult with the Physician Assistant Committee, the Medical Board only has jurisdiction over its licensees, and can only impose regulations on physicians. For that reason, the Board must focus on the issues relating to physicians and their responsibilities, including their responsibilities as supervisors of allied health professionals. For that reason, the following discussion is confined to the issues as they relate to physicians.

Use of unlicensed or inappropriately licensed personnel by physicians:

Current law prohibits the use of lasers by non-licensed or inappropriately licensed persons. Only physicians may legally use these devices, or they may delegate the laser's use on **their** patients to physician assistants, registered nurses, and nurse practitioners under their supervision. Regardless of supervision, physicians may not delegate laser use to non-licensed medical assistants, licensed estheticians or other inappropriately licensed persons.

Lack of supervision, inappropriate delegation, and lack of review of nurses' performance:

While current law allows the delegation of laser treatments to the above mentioned licensees, the law requires supervision by the physician. Standardized procedures for nurses, and delegation of services agreements for physician assistants, allow the procedures to be performed while the physician is not on-site, however, they do not absolve physicians from their supervision responsibilities.

Many of the comments made at the forums address the current, illegal practice of "rent-a-license," that is to say, becoming a paper-only supervisor while providing little, or, in many cases, absolutely no supervision to the nurses or physician assistants. Current law prohibits this practice.

Under the standardized procedure guidelines, physicians may only delegate to nurses they know to be capable of performing the delegated task. (This is true for lasers, and any other procedure in any specialty.) The guidelines require that the experience, training, and education requirements for performance of the delegated function be documented, and that a method of initial and continuing evaluation of the nurses' competence be established.

Standardized procedure guidelines require that functions performed be in an "Organized Health Care System." When the regulations were promulgated jointly by the Nursing and Medical Boards

in the 1970s, both Boards envisioned nurses practicing in healthcare settings, not beauty salons. Legally, nothing has changed since the promulgation of the regulations. Nurses must perform procedures in a health-care setting, under all of the standardized procedure guidelines. (Attached) The law does not allow a nurse to set-up a practice in a salon, hire a physician supervisor, and perform medical procedures independently.

The guidelines further require that circumstances be articulated "which the registered nurse is to immediately communicate with a patient's physician concerning the patient's condition." This implies two things: 1) that the patient is the physician's responsibility, and; 2) that there be a means in which to immediately contact the supervising physician. Delegation of the procedure to the nurse does not absolve physicians from their responsibility to their patients. While there is no actual mileage limit in the law relating to supervision, this requirement certainly means that the physician must be immediately reachable. According to the materials on the BRN's website, relating to Nurse Practitioners, who have much greater autonomy than registered nurses, it states:

"The mileage between the nurse practitioner and the supervising physician is not specifically addressed in the NPA. However, the physician should be within a geographical distance, which enables her/him to effectively supervise the nurse practitioner in the performance of the standardized procedure functions."

There has been much said over the years about the lack of legal definition of supervision. A legal definition might be helpful, but a simple dictionary may do the job:

According to *Webster's Encyclopedic Dictionary of the English Language*,
"supervise, to oversee for direction; to superintend; to inspect.
supervision, the act of supervising; superintendence; direction
supervisor, one who supervises; and overseer, an inspector, a superintendent."

According to *Funk & Wagnalls Standard College Dictionary*,
Supervise: to have charge of directing
Supervision: the act of supervising
Supervisor: one who supervises or oversees; superintendent; inspector

Random House defines "supervise" as "to oversee (a process, work, workers, etc.) during execution or performance; superintend; have the oversight and direction of."

A physician who is, on paper, a supervisor, who does not give direction, oversee or inspect, is not, in plain English, performing the task of supervising.

Physician assistant (PA) supervision guidelines are articulated more specifically. (Regulations attached) To supervise a PA, the regulatory requirements are:

- All care provided to the patient by a PA is the ultimate responsibility of the physician.
- Physicians are limited to supervising no more than four PAs at any moment in time.

- Physicians must be in the same facility as the PA or be immediately available by electronic communication.
- Before authorizing PAs to perform any procedure, the physician is responsible for evaluating the PA's education, experience, knowledge, and ability to perform it safely and competently.
- PAs may not own a medical practice (although they may own up to 49% of the stock in a professional medical corporation.)
- PAs may not hire their supervisors.

There are four methods in which physicians may provide supervision:

- 1) Physician sees the patient the same day as they are treated by PA, or;
- 2) The physician reviews, signs and dates the medical record of every patient treated by the PA within 30 days of treatment, or;
- 3) The physician adopts written protocols to guide the specific actions of the PA. The physician must select, review, sign, and date at least 5% of the medical records of patients treated under the protocols within 30 days of the treatment, or;
- 4) Under special circumstances, the physician provides supervision through additional methods which must be approved in advance by the Physician Assistant Committee.

While the PA regulations are written more specifically, they are not unlike the nursing regulations. The nursing law and regulations, while written more broadly, require that physicians be responsible for their patients, supervise the nurse, including the evaluation of their training and competence. They also do not allow nurses to hire their supervisor or solely own the practice. While the nursing regulations do not require a specific percentage of cases that must be reviewed, the regulations do require evaluations, which cannot be done without any review of cases.

Lack of Qualifications of Supervisors:

Physicians may only delegate to those that they know to be capable of performing the delegated task. If they are to supervise the task, it can be implied that 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 term "core physician" was used in the forum discussions, meaning that a supervising physician specialized in an area that is appropriate to supervise the use of laser treatments, such as plastic surgery, cosmetic surgery, or dermatology. In PA regulations, PAs cannot be delegated tasks outside of the physician's customary practice.

While nursing regulations are less specific, again, the regulations still require supervision. Current law allows for nurses to be supervised by physicians in any specialty, however, the physicians must fulfill their supervision obligations. The regulations imply that this would include, regardless of the primary specialty or certification of the physician, being proficient in the procedure being delegated so that they are capable of providing direction, guidance and evaluation.

Lack of training or certification:

Medicine is in constant change. Physicians who have been practicing for 20 years will not be practicing in the same manner as they were when they graduated from medical school. As knowledge and technology improves, the practice of medicine evolves.

Physicians are licensed after obtaining their medical degree, completing their postgraduate training, and passing the licensing examinations. While not legally required, most physicians continue their education through specialty postgraduate training and will become board-certified in a specialty. They are not retested or required to go back to medical school every time there is a scientific discovery, a new medicine is approved, or a new surgical technique developed. Physicians over 50-years-old practicing plastic surgery or dermatology, for example, may not have learned how to perform liposuction in their formal post-graduate medical training. No "liposuction license" is granted, and no examination or certification for the procedure is given. Physicians learn new techniques from training courses, colleague mentoring, and preceptorships, and they are legally able to practice these procedures without any kind of specialty or procedural certification.

Similarly, registered nurses do not have specialized licenses, and become specialized in specific procedures through experience and training in their practice environment. Specialty courses also exist, and some provide certification. Most certificates granted, however, have no legal standing. Many of the nurses testifying at the forums stated they had taken courses in laser use and had been certified. While it is laudable that they completed training, there are no national certification standards in the procedure, and no nationally or state approved certification standards, making the certification, legally speaking, without meaning. It is the supervising physicians that are responsible for evaluating the qualifications of the nurses to whom they are delegating regardless of whether they have been "certified" or not.

Lack of back-up systems and emergency plans:

As established by existing laws and regulations, physicians performing or delegating treatments are responsible for their patients' care. As supervisors, they are responsible to ensure back-up systems and emergency plans. Under current law, the patients are the physicians' responsibility, and they are responsible for treating mishaps, complications or any other emergency that might arise from the treatments they delegated. While nurses are responsible for their patients within their scope-of-practice, under the Medical Practice Act, physicians have the ultimate responsibility for the care of their patient.

Lack of appropriate prior examination:

The delegation of the patients' prior appropriate examination may only be delegated to nurse practitioners, not to registered nurses. For furnishing or ordering drugs or prescriptive devices, the examination may be delegated to a nurse practitioner functioning under standardized procedures. As B&P Code Section 2836.1 was added in 2004 by AB 2560 (Montanez; Chap. 205, Statutes of 2004) to grant this authority to nurse practitioners, it is clear that no such authority is granted to registered nurses.

Physician Assistants may be delegated the "prior appropriate examination" as long as their regulations are followed, which are much more stringent and specific than RN standardized

procedure guidelines. The PA must be working for a physician specialist in cosmetic medicine, and the requirements of the supervisor are much more specific, as explained above.

Lay-owned businesses – violation of corporate practice bar:

California law prohibits the corporate practice of medicine. Laypersons or lay entities may not own any part of a medical practice. (Business & Professions Code Section 2400)

In an attempt to circumvent this legal prohibition, some have created some business and management schemes that violate the law. Businesses that provide management services, franchises or other models that result in any unlicensed person or entity influencing or making medical decisions is in violation of the law.

As an example, businesses that control medical records, the hiring and firing of healthcare staff, decisions over coding and billing, the approving of or selecting medical equipment or drugs, violate the law. Management Service Organizations (MSO) 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) would be illegal. Also, many current business arrangements violate the prohibition against fee-splitting or giving any consideration for patient referrals (B&P 650). The current practice of lay-owned businesses hiring a medical director is also prohibited.

Physicians who become employees of lay-owned spas and violate other business provisions of laws may be disciplined for unprofessional conduct.

Procedures performed in inappropriate settings:

Current law allows physicians to perform laser treatments in any setting, including salons. They may not, however, be paid by or hired by the salon, nor may they pay for referrals or split fees with the salon or any other entity. Nurses providing laser treatments delegated under standardized procedures must perform them in an "organized healthcare system." The same is true for PAs.

Lack of patient informed consent and education:

Consumers generally view procedures as they are marketed. If laser treatments are advertised in the same manner as facials or hair services, it is not surprising that customers are not fully aware of their medical nature, or conscious of their risks. All medical procedures must be preceded by informed consent, which would include the possible risks associated with the treatment. While there is no specific code that enumerates what must be told to patients, the well-established doctrine of informed consent in case law requires that patients must be, at a minimum, informed of:

- 1) the nature of the treatment,
- 2) the risks, complications, and expected benefits, including its likelihood of success, and
- 3) Any alternative to the recommended treatment, including the alternative of no treatment, and their risks and benefits.

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

There are often violations of advertising law as well. Business & Professions Code Section 2272 requires advertising to include the physician's name, or the name for which they have a fictitious name permit. While the nurses may be performing the treatment, the name of the supervising physician, or his or her registered fictitious name, must be in the advertisement.

There is also a need for the Boards to do more in educating patients, which is discussed below.

Enforcement and Public Education

The following is confined to the enforcement procedures and actions of the Medical Board.

Current Enforcement

The Medical Board's enforcement actions and their priorities are dictated by law. Section 2220.05 of the Business and Professions Code establishes the priority in which cases are to be handled, which are:

- 1) Gross negligence, incompetence, or repeated negligent acts that involve death or serious bodily injury to one or more patients;
- 2) Drug or alcohol abuse by the physician involving death or injury to a patient;
- 3) Repeated acts of clearly excessive prescribing, furnishing, or administering of controlled substances, or repeated acts of doing so without a good-faith prior examination;
- 4) Sexual misconduct with one or more patients during the course of treatment or examination;
- 5) Practicing medicine while under the influence of drugs or alcohol.

Cases involving laser procedures generally do not fall into the above categories. The most common issues relating to these types of treatments are:

- Corporate Practice:

As a result of the legally set priorities and limited investigative staff, in 2002 the enforcement program reviewed corporate practice of medicine cases. At that time, the staff's handling of the cases was to inform the physician and unlicensed person or firm that they appeared to be in violation of the law and obtain compliance, and, in some instances, issue a citation. These cases were complex and necessitated substantial legal resources, resulting in long timeframes to complete these cases. According to the consulting Deputy Attorney General, in order for citations to be issued, more information was required from investigation to prove violations.

In 2004, after a meeting of staff of the Medical Board and Attorney General staff, it was decided that corporate practice cases would not be investigated unless there was patient harm. If sufficient evidence was present without investigation, then action would be taken.

Complaints relating to corporate practice rarely involve patient harm, and generally are received from competitors, not patients. Actions have been taken for unlicensed practice and violating the corporate practice bar, including a recent case that has been adopted as a precedential decision. In addition, there is an accusation pending against a physician for

gross negligence in their supervision of nurses while acting as a "medical director" for a laser business. Both cases, however, involve patient harm.

- Advertising:

Cases involving advertising violations are generally handled without being sent to the field for investigation. Physicians are issued a letter that they are in violation of the law. If they comply and cease violating the law, no further action is taken. If not, they are generally handled through the citation process. Most complaints relating to advertising are received from competitors, not patients.

- Lack of adequate supervision:

As we have heard from the testimony, while there has certainly been instances of patient harm, there have been no deaths or life-threatening injury reported in California as a result of laser treatments. (There was one story of undiagnosed skin cancer presented in the testimony at the first forum; however, it was not noted whether it was a patient in California, and if so, whether a complaint had been filed with the Medical Board.) Under current Medical Board procedures, only those involving patient harm will be sent to the field for investigation to build a case for formal disciplinary action.

If there is no physician involvement, or if there appears to be only nurse involvement, the Medical Board will refer the case to the Nursing Board for their action.

Future Enforcement Opportunities:

- Re-establishment of "Operation Safe Medicine" (OSM)

In 2000, the Medical Board had a unit in its enforcement program called "Operation Safe Medicine." It was dedicated to the unlicensed practice of medicine and actively worked to discover unlicensed medical clinics and unlicensed persons soliciting patients. A number of celebrated cases came from their work, and it was very effective in addressing the problem of unlicensed clinics that primarily preyed on certain ethnic populations, as well as other types of unlicensed practice. Unfortunately, due to the budget reduction in 2002, the unit was disbanded and remaining staff was re-directed to general enforcement.

At the November 2007 Board meeting, the members approved the re-establishment of OSM. If successful in obtaining adequate staff positions and an allocation of funds through the State's budgetary process, this unit may be able to dedicate staff to the enforcement of the laws relating to laser procedures.

- Increase the Use of the Citation and Fine Process for Violators:

There are opportunities to utilize the citation and fine process in cases that do not involve patient harm, especially those involving advertising and business violations. The current law authorizes the Board to issue citations and fines, and while the issuing of a citation may take less time than a formal accusation, it must be proven by a preponderance of evidence. There

is significant due process granted to physicians, requiring presentation of evidence and a hearing, if requested.

At the forums, it was suggested that a significant fine be established by legislation to address these issues. However, it is too early to suggest this proposal, as the Medical Board needs to re-establish the OSM Unit to determine if a more aggressive citation program is a deterrent and addresses the advertising and corporate practice violations.

- Re-direction of Resources:

The purpose of the law setting enforcement priorities is clearly to protect the public from serious harm. While there has been some harm done to patients, and there certainly is a potential for patient harm, laser treatments do not generally fit into the top five priorities established. The Board could certainly make it their priority and direct more aggressive enforcement of advertising and corporate practice statutes, however, that shift in resources would be at the cost of other cases. It is difficult to argue that a laser hair removal advertising case should take priority over the investigation of a grossly negligent and incompetent cardiologist or a surgeon operating while under the influence of drugs.

Any redirection of resources to aggressively enforce cases outside of the statutorily established priorities, without any increase in allocation of funds and employees, would result in less effective and slower enforcement of more dangerous practices.

- Better communication and coordination between the Boards:

At the forum on September 13, we heard testimony from a patient advocate about his experience with filing complaints with the Board, with unsatisfactory results. In several of the presented cases, the complaint involved nurses who he alleged were practicing without supervision. In these types of cases, where there is no supervising physician identified, they are sent to the Nursing Board for action. If their investigation results in no disciplinary action against the nurse, there may still be violations of the law by the supervising physician. In the instances presented, if physicians were involved, there may have been violations of advertising and fictitious name permit requirements.

While the Boards' enforcement staffs regularly communicate and cooperate on investigations, it is possible that a more formal procedure should be developed to ensure that cases referred are also referred back for action.

Education of Licensees and Patients:

The testimony presented at the forums demonstrated that licensees are not fully educated in the law, and patients often lack understanding of the medical nature of laser treatments. The Boards need to do a better job of educating licensees and patients.

Public education materials and outreach efforts need to be developed to inform patients of the medical nature of the treatments. They also need to be informed that, even if nurses are providing

the treatment, the physician has ultimate responsibility for their care and safety. While physicians have the responsibility to provide adequate informed consent to their patients, the Board needs to do a better job of ensuring patients are better aware of the risks, as well as their rights.

Licenseses may also need to be reminded that these procedures are governed by the same laws and regulations as any other medical practice. Frequently, there has been the tendency to view them as something other than medical, even by some licensees. Physicians need to be fully informed of their legal responsibilities, and the laws that govern their practice, including laws relating to the business of medicine and advertising.

Discussion of Future Actions of the Board/Recommendations

The public forums held jointly by the Medical and Nursing Boards have accomplished their purpose of gathering information. The Boards now have a greater understanding of the issues, how practices may be violating current law, the risks of injury, the lack of understanding of licensees and patients, and how the lack of enforcement may have contributed to the risks and violations.

It appears there may be no need for further laws or regulations, but there is a need for enforcement resources to enforce the laws and regulations already in effect. The development of a strategy or method to enforce current laws should precede any efforts to seek any additions or amendments.

The members must review the issues relating to laser safety and take any action they deem necessary by January 1, 2009. Members should discuss the following possible solutions:

Recommendations

Short Term:

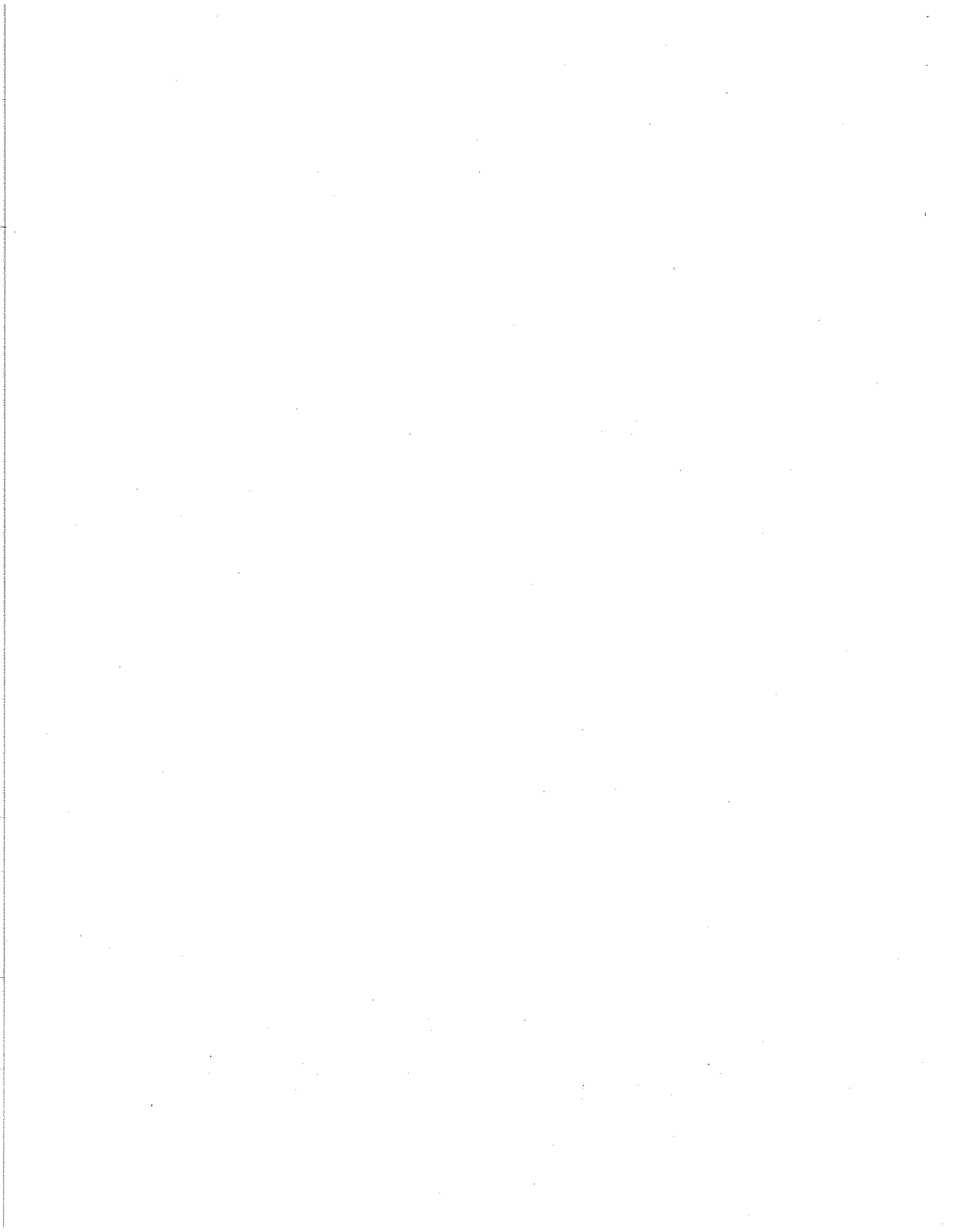
- Publish a statement clearly outlining the current law and the responsibilities of physicians in providing laser treatments. A draft article is attached, and staff would ask the Board's approval to publish it in the Board's Newsletter and on its Web site.
- Re-write and distribute "Medical Spa – What You Need to Know," an article for consumers. The draft of the article is attached, and staff would ask that the Board approve it for publication and distribution.

Long Term:

- Affirm that it is the Board's intention to support the reestablishment of "Operation Safe Medicine" which, in addition to addressing unlicensed practice, will work to enforce the laws relating to cosmetic procedures;
- Direct staff to work with the Nursing Board to develop an enhanced communication system in cases involving physicians and nurses;
- Direct staff to use the citation and fine process to deter further violations; and

- Direct staff, after all action is taken, and before January 1, 2009, to report to the Legislature on the Board's actions and intentions.

This paper is not intended to cover all of the points raised at the forums or problems identified. It is a summary of the major concerns raised, how the current laws may apply to physicians, and the possible solutions that should be considered.



Relevant Laws and Regulations:

Business & Professions Code Section 2023.5, Medical & Nursing Boards to Study Safety of Lasers & Intense Pulse Light Devices in Elective Cosmetic Procedures

(a) The board, in conjunction with Board of Registered Nursing, and in consultation with the Physician Assistant Committee and professionals in the field, shall review issues and problems surrounding the use of laser or intense light pulse devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants. The review shall include, but need not be limited to, all of the following:

- (1) The appropriate level of physician supervision needed.
- (2) The appropriate level of training to ensure competency.
- (3) Guidelines for standardized procedures and protocols that address, at a minimum, all of the following:
 - (A) Patient selection.
 - (B) Patient education, instruction, and informed consent.
 - (C) Use of topical agents.
 - (D) Procedures to be followed in the event of complications or side effects from the treatment.
 - (E) Procedures governing emergency and urgent care situations.

(b) On or before January 1, 2009, the board and the Board of Registered Nursing shall promulgate regulations to implement changes determined to be necessary with regard to the use of laser or intense pulse light devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants.

Business & Professions Code Section 2400 – Corporate Practice of Medicine

Corporations and other artificial legal entities shall have no professional rights, privileges, or powers. However, the Division of Licensing may in its discretion, after such investigation and review of such documentary evidence as it may require, and under regulations adopted by it, grant approval of the employment of licensees on a salary basis by licensed charitable institutions, foundations, or clinics, if no charge for professional services rendered patients is made by any such institution, foundation, or clinic.

Business & Professions Code Section 2264 – Aiding & Abetting Unlicensed Practice of Medicine

The employing, directly or indirectly, the aiding, or the abetting of any unlicensed person or any suspended, revoked, or unlicensed practitioner to engage in the practice of medicine or any other mode of treating the sick or afflicted which requires a license to practice constitutes unprofessional conduct.

Business & Professions Code Section 2266 – Physician's Responsibility to Maintain Medical Records

The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct.

Business & Professions Code Section 2272 – Advertising Must Include Physician’s Name or FNP Name

Any advertising of the practice of medicine in which the licensee fails to use his or her own name or approved fictitious name constitutes unprofessional conduct.

Business & Professions Code Section 2273 – Employment of Runners, Cappers, Steerers, and others to procure patients

(a) Except as otherwise allowed by law, the employment of runners, cappers, steerers, or other persons to procure patients constitutes unprofessional conduct.

(b) A licensee shall have his or her license revoked for a period of 10 years upon a second conviction for violating any of the following provisions or upon being convicted of more than one count of violating any of the following provisions in a single case:

Section 650 of this code, Section 750 or 1871.4 of the Insurance Code, or Section 549 or 550 of the Penal Code. After the expiration of this 10-year period, an application for license reinstatement may be made pursuant to Section 2307.

Business & Professions Code Section 650 – Payment for Patient Referrals/Fee Splitting

(a) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code, the offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest or coownership in or with any person to whom these patients, clients, or customers are referred is unlawful.

(b) The payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer.

(c) The offer, delivery, receipt, or acceptance of any consideration between a federally-qualified health center, as defined in Section 1396d(l)(2)(B) of Title 42 of the United States Code, and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to the health center entity pursuant to a contract, lease, grant, loan, or other agreement, if that agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center, shall be permitted only to the extent sanctioned or permitted by federal law.

(d) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2, it shall not be unlawful for any person licensed under this division to refer a person to any laboratory, pharmacy, clinic (including entities exempt from licensure pursuant to Section 1206 of the Health and Safety Code), or health care facility solely because the licensee has a proprietary interest or coownership in the laboratory, pharmacy, clinic, or health care facility; provided, however, that the licensee's return on investment for that proprietary interest or coownership shall be based upon the amount of the capital investment or proportional ownership of the licensee which ownership interest is not based on the number or value of any patients referred. Any referral excepted under this section shall be unlawful if the prosecutor proves that there was no valid medical need for the referral.

(e) (1) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2, it shall not be unlawful to provide nonmonetary remuneration, in the form of hardware, software, or information technology and training services, necessary and used solely to receive and transmit electronic prescription information in accordance with the standards set forth in Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104) in the following situations:

(A) In the case of a hospital, by the hospital to members of its medical staff.

(B) In the case of a group medical practice, by the practice to prescribing health care professionals that are members of the practice.

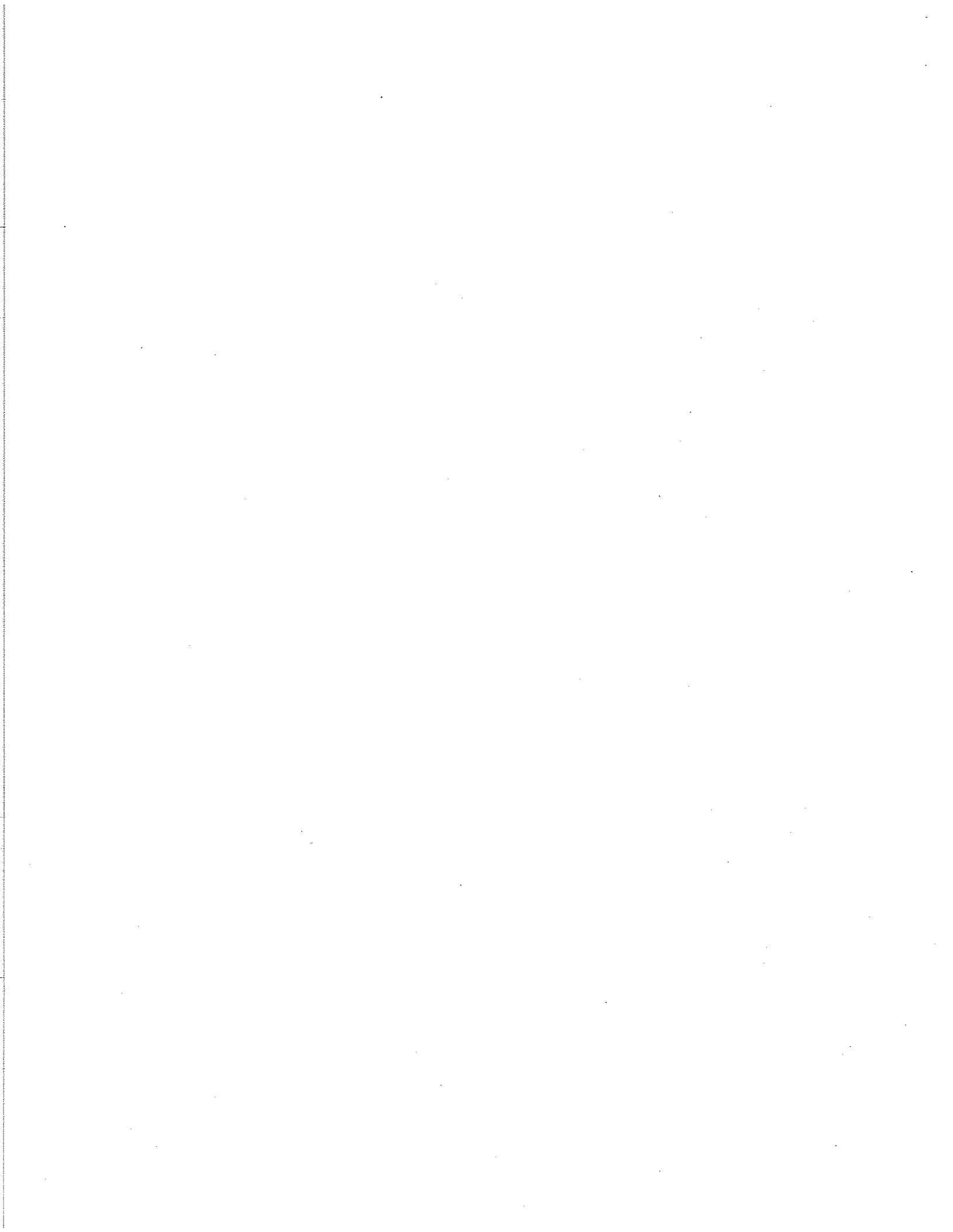
(C) In the case of Medicare prescription drug plan sponsors or Medicare Advantage organizations, by the sponsor or organization to pharmacists and pharmacies participating in the network of the sponsor or organization and to prescribing health care professionals.

(2) The exceptions set forth in this subdivision are adopted to conform state law with the provisions of Section 1860D-4(e)(6) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104) and are limited to drugs covered under Part D of the federal Medicare Program that are prescribed to Part D eligible individuals (42 U.S.C. Sec. 1395w-101).

(3) The exceptions set forth in this subdivision shall not be operative until the regulations required to be adopted by the Secretary of the United States Department of Health and Human Services, pursuant to Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395W-104) are effective. If the California Health and Human Services Agency determines that regulations are necessary to ensure that implementation of the provisions of paragraph (1) is consistent with the regulations adopted by the Secretary of the United States Department of Health and Human Services, it shall adopt emergency regulations to that effect.

(f) "Health care facility" means a general acute care hospital, acute psychiatric hospital, skilled nursing facility, intermediate care facility, and any other health facility licensed by the State Department of Health Services under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(g) A violation of this section is a public offense and is punishable upon a first conviction by imprisonment in the county jail for not more than one year, or by imprisonment in the state prison, or by a fine not exceeding fifty thousand dollars (\$50,000), or by both that imprisonment and fine. A second or subsequent conviction is punishable by imprisonment in the state prison or by imprisonment in the state prison and a fine of fifty thousand dollars (\$50,000).



Physician Assistant Regulation:

BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS
TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS
DIVISION 13.8. PHYSICIAN ASSISTANT EXAMINING COMMITTEE OF
THE MEDICAL BOARD
OF CALIFORNIA
ARTICLE 4. PRACTICE OF PHYSICIAN ASSISTANTS

S 1399.545. Supervision Required.

- (a) A supervising physician shall be available in person or by electronic communication at all times when the physician assistant is caring for patients.
- (b) A supervising physician shall delegate to a physician assistant only those tasks and procedures consistent with the supervising physician's specialty or usual and customary practice and with the patient's health and condition.
- (c) A supervising physician shall observe or review evidence of the physician assistant's performance of all tasks and procedures to be delegated to the physician assistant until assured of competency.
- (d) The physician assistant and the supervising physician shall establish in writing transport and back-up procedures for the immediate care of patients who are in need of emergency care beyond the physician assistant's scope of practice for such times when a supervising physician is not on the premises.
- (e) A physician assistant and his or her supervising physician shall establish in writing guidelines for the adequate supervision of the physician assistant which shall include one or more of the following mechanisms:
 - (1) Examination of the patient by a supervising physician the same day as care is given by the physician assistant;
 - (2) Countersignature and dating of all medical records written by the physician assistant within thirty (30) days that the care was given by the physician assistant;
 - (3) The supervising physician may adopt protocols to govern the performance of a physician assistant for some or all tasks. The minimum content for a protocol governing diagnosis and management as referred to in this section shall include the presence or absence of symptoms, signs, and other data necessary to establish a diagnosis or assessment, any appropriate tests or studies to order, drugs to recommend to the patient, and education to be given the patient. For protocols governing procedures, the protocol shall state the information to be given the patient, the nature of the consent to be obtained from the patient, the preparation and technique of the procedure, and the follow-up care. Protocols shall be developed by the physician, adopted from, or referenced to, texts or other sources. Protocols shall be signed and dated by the supervising physician and the physician assistant. The supervising physician shall review, countersign, and date a minimum of 10% sample of medical records of patients treated by the physician assistant functioning under these protocols within thirty (30) days. The physician shall select for review those cases which by diagnosis, problem, treatment or procedure represent, in his or her judgment, the most significant risk to the patient;
 - (4) Other mechanisms approved in advance by the committee.

(f) In the case of a physician assistant operating under interim approval, the supervising physician shall review, sign and date the medical record of all patients cared for by that physician assistant within seven (7) days if the physician was on the premises when the physician assistant diagnosed or treated the patient. If the physician was not on the premises at that time, he or she shall review, sign and date such medical records within 48 hours of the time the medical services were provided.

(g) The supervising physician has continuing responsibility to follow the progress of the patient and to make sure that the physician assistant does not function autonomously. The supervising physician shall be responsible for all medical services provided by a physician assistant under his or her supervision.

Note: Authority cited: Sections 2018, 3502 and 3510, Business and Professions Code.
Reference: Sections 3502 and 3516, Business and Professions Code.

HISTORY

1. Renumbering and amendment of former section 1399.522 to section 1399.545 filed 9-20-83; effective thirtieth day thereafter (Register 83, No. 39).
2. Amendment filed 7-12-85; effective thirtieth day thereafter (Register 85, No. 28).
3. Amendment of subsection (e)(3) and repealer of subsection (g) and relettering filed 1-28-92; operative 2-27-92 (Register 92, No. 12).

16 CCR s 1399.545, 16 CA ADC s 1399.545

1CAC

16 CA ADC s 1399.545

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Medical Board of California Regulation: Physicians must comply with Standardized Procedure Guidelines:

Article 4. Standardized Procedure Guidelines

1379. Standardized Procedures for Registered Nurses.

A physician and surgeon or a podiatrist who collaborates in the development of standardized procedures for registered nurses shall comply with Title 16 California Administrative Code Sections 1470 through 1474 governing development and use of standardized procedures.

NOTE: Authority cited: Sections 2018 and 2725, Business and Professions Code. Reference: Section 2725, Business and Professions Code.

HISTORY:

1. Renumbering and amendment of former Article 4 (Sections 1376-1377.1) to Article 2 (Sections 1366 and 1366.1), and new Article 4 (Section 1379) filed 8-3-83; effective thirtieth day thereafter (Register 83, No. 32). For prior history, see Registers 81, No. 32; and 78, No. 17.

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.

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 & 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 health care 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))

In an attempt to circumvent this legal prohibition, some creative business and management schemes have emerged that violate the law. 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.

As an example, businesses that control medical records, the hiring and firing of healthcare staff, decisions over coding and billing, and the approving or selection of medical equipment or drugs, violate 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 violate other business provisions of 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, under 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:

- 1) the nature of the treatment,
- 2) the risks, complications, and expected benefits, including its likelihood of success, and
- 3) 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 & 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 ads not be misleading. California law is very specific in prohibiting many of the advertising practices currently 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 & Professions Code Section 651, may be viewed on the Medical Board's website: www.mbc.ca.gov.

The Bottom Line:

Cosmetic procedures are the practice of medicine, and physicians are responsible for their patients, regardless of who performs the treatments. There is no legal scheme that allows physicians to collect a fee for signing their name to an agreement to lend their license to an entity to practice medicine. Legally, the "clients" of the spa or salon are patients --- the *physician's* patients, and that arrangement comes with all of the responsibility *and liability* that goes with any other doctor-patient relationship. Becoming involved in an improper business arrangement, may, in the short term, raise a physician's economic bottom line. In the long run, however, the risks are great. In reality, the bottom line is that physicians who become embroiled in these illegal arrangements may lose their license, or their livelihoods.

It is impossible to cover all of the relevant legal issues in this short article, and the content is not a substitute for professional legal advice. Physicians may want to consult with their attorneys or malpractice carriers for additional legal advice.

Medical Spas

Medical Spa. It sounds so soothing. It evokes images of candles, beautiful music, warmth and papering. Spahhhh! The word itself makes one relax.

Medical Spas are marketing vehicles for medical procedures. The use of the term "spa" is for advertising purposes to make the procedures seem more appealing. In reality, however, they're the practice of medicine.

There's no harm in seeking pampering or in wanting to look better. A visit to a spa may provide a needed respite from our stressful lives, and treatments that makes us look better often makes us feel better. Those of us at the Medical Board, however, become concerned when medicine is marketed like a pedicure, and consumers are led to believe that being injected, lasered, and resurfaced requires no more thought than changing hair-color.

Wrong. Medical treatments should be performed by medical professionals. There is risk to any procedure, however minor, and consumers should be aware of the dangers. While it is illegal for non-licensed personnel to provide these types of treatments, consumers should know that there are persons and firms operating illegally. Cosmetologists, 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 licensed physician, or a licensed registered nurse or physician assistant under the supervision of a physician.

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

- 1) Know who will perform the procedure and their licensing status:

If a physician is performing the treatment, you should ask about his or her qualifications. Is the doctor a specialist in these procedures? Is he or she board certified in an appropriate specialty? Licensing status may be verified at the Board's website: www.mbc.ca.gov. Board certification status may be verified at www.abms.org.

If a nurse or physician assistant will be doing the procedure, what are their qualifications? Where is the doctor supervising them? Are they really being supervised, or are they acting alone with a paper-only supervisor? Again, you should check the supervising doctor's credentials, as well as the nurse's or physician assistant's. Those websites are www.rn.ca.gov and www.physicianassistant.ca.gov.

An appropriate examination must be conducted before treatments are performed. This exam must be conducted by a physician, or the doctor may delegate the examination to licensed nurse practitioners or physician assistants. Physicians may not delegate this examination to registered nurses.

- 2) Be fully informed of 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. If procedures are being heavily marketed, with high-pressure sales techniques promising unrealistic results, run.

- 3) 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. If you observe dirty conditions, or notice that the personnel does not wash their hands before approaching you, find another facility.

4) Ask about complications, and who is available to handle them:

In the event you should have an adverse reaction, you want to know who will be there to help. Who should you call, and what hospital or facility is available where the doctor can see you? If you get an unsatisfactory answer that minimizes your concerns, or they don't have an answer, find someone else. Qualified physicians have facilities or privileges at hospitals where they can handle emergencies. If they don't, that's cause for concern.

5) 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 sub-standard prices, there's a good probability that what they are advertising is not what will be delivered. Genuine Botox, Collagen, Restalyne, and other injections are pricey. If someone is offering an injection for \$50, when the going rate at doctors' offices is \$500, then you can be sure it's not the real McCoy. There have been tragic cases of unscrupulous practitioners injecting industrial silicone and toxic counterfeit drugs that have made patients critically ill, caused disfigurement, or killed them.

Cosmetic procedures, at best, can boost one's mood and appearance. At worst, they can kill you. Don't trust your health, your skin, or your face to the unqualified or unscrupulous. Know that there is a substantial financial cost to obtaining qualified treatments, as well as some risk. If you want the best results, do your homework and only trust those who demonstrate competence and caution.