

Protecting Patient Safety

Appropriate Training and Supervision for Cosmetic and Laser Medical Procedures

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EXHIBIT P - LASERS
Document consists of 27 pages.
Entire exhibit provided.
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“NON-INVASIVE” COSMETIC MEDICAL PROCEDURES UP 700% SINCE 1997

Over 11 million cosmetic medical procedures performed in 2006, of those, 9.1 million procedures considered “minimally invasive:”

Top 5:

- **Botox®**
- **Chemical peels**
- **Laser Hair Removal & Other Laser Procedures**
- **Microdermabrasion**
- **Hyaluronic acid fillers**

Source: “Having a Little Work Done at the Mall,” New York Times, January 13, 2008

AVAILABILITY OF COSMETIC MEDICAL PROCEDURES IN NON- TRADITIONAL MEDICAL SETTINGS IS ON THE RISE

“In the past three years, the number of medical spas has more than tripled to about 1,500, according to estimates from the International Medical Spa Association. “

-*Wall Street Journal*, “Medspa Boom Has Become a Bust for Some,” Nov. 21, 2006

LAWS, REGULATIONS AND DEFINITIONS IN STATE MEDICAL ACTS HAVE NOT KEPT UP WITH NEW PROCEDURES AND TECHNOLOGY

- **More than 20 states have no laws addressing whether or not laser medical procedures can be delegated, to whom and under what circumstances**
- **Even fewer states have laws relating to cosmetic injectables and chemical peels**
- **Many states have no definition of the practice of medicine which encompasses cosmetic medical procedures**

BUT THAT IS CHANGING. AT LEAST 15 STATES ARE CURRENTLY IN THE PROCESS OF AMENDING OR CREATING NEW LAWS RELATING TO THIS ISSUE

There are several provisions under which legal issues relating to laser medical procedures can fall. These include but are not limited to:

- **Definition of the practice of medicine**
- **Definition of physician supervision**
- **False and deceptive advertising**
- **Corporate practice of medicine**
- **Maintenance of medical records**
- **Patient assessment requirements**
- **Facility license requirements for medspas**
- **Limit to number of remote facilities**
- **Sale of medical devices**

AMERICAN SOCIETY FOR DERMATOLOGIC SURGERY (ASDS) PATIENT SAFETY SURVEY

**A survey of physicians showed that in the
past year:**

**65% of respondents treated
complications caused by a
non-physician**

**92% of respondents treated
patients with skin cancer,
some of which resulted in
patient mortality, which was
either overlooked or
misdiagnosed by a non-physician.**

ASDS PATIENT SAFETY SURVEY

The top three complications included:

Burns and scarring from laser hair removal

Misdiagnosis of skin cancer

Burns and scarring from chemical peels

TRAINING ON THE USE OF THE LASERS THEMSELVES IS LEAST IMPORTANT TO LASER SAFETY....

“It is a truism in cutaneous laser therapy that firing a laser handpiece may be the least important portion of the treatment; it is everything but the actual treatment, including patient selection, parameter selection, and recognition and management of undesirable outcomes, that requires judgment and training.”

From “Use of Cutaneous Lasers and Light Sources: Appropriate Training and Delegation” Alam, M.; Dover, J.S.; Arndt, K.A.; Skin Therapy Lett. 2007;12(5):5-9.

RESULTS FROM A STUDY ON COSMETIC MEDICAL PROCEDURE COMPLICATIONS

- **82% of all complications occurred in facilities that had no direct (on-site) physician supervision**
- **Of these, 57% were in facilities with a “medical director” with limited training in dermatologic procedures and light-based therapy**
- **Of all the complications, 78% occurred in non-traditional medical facilities, such as free standing medical spas and laser centers in shopping malls**

From “Complications from Laser Procedures Performed by Non-Physicians” by Vic A. Narurkar, MD,, Skin & Aging 2005;13(9):70-71.

PATIENT OR POTENTIAL LASER CLIENT?

- **“In the spa environment or in a poorly supervised laser practice, the pressure to ‘convert’ all consultations into treatments may result in poor patient selection, which in turn may dramatically increase the rate of adverse events.”**
- **“Incentives for non-physician providers to maximize revenue generation in a spa or thinly supervised setting can increase the risk of adverse events by:**
 - hurrying preoperative evaluation and laser treatment.**
 - encouraging the treatment of patients who may be poor laser candidates.”**

INAPPROPRIATE DIAGNOSIS/MISSED CANCER DIAGNOSIS



**Patient seen by nurse without
physician examination, for
“pigmentation spots” on right
cheek**

**Received 3 treatments with Q-
switch YAG laser**

**Patient seen 11 months later
by Dermatologist with
subcutaneous mass**

**Bx diagnosis: “Amelanotic
melanoma, locally metastatic”**

UNTRAINED, UNSUPERVISED PRACTITIONER

**Laser sunspot
removal at a
Florida medspa
using intense
pulsed-light.
Patient treated by
cosmetologist.
Nurse owned spa
but was not on-
site.**



INCORRECT DEVICE/SETTING FOR SKIN TYPE



Laser Hair Removal by a non-physician in a CA mall medspa at a setting too high for African American skin.

Patient is currently suing spa.

HYPERPIGMENTATION, HYPOPIGMENTATION & SCARRING



Resulting from the use of a laser by a non-physician for hair removal

BURNS FROM LASER HAIR REMOVAL



PULSED LIGHT WITHOUT COOLING, DIRECT APPLICATION ON SKIN



HERPES SIMPLEX INFECTION POST LP1064 LASER FOR HAIR REDUCTION



FATAL REACTIONS

- **22-year-old Shiri Berg – hair removal treatment at a “Day Spa” in North Carolina. Applied lidocaine cream from her waist to her ankles and wrapped her legs in plastic wrap**
- **Patient suffered heart failure and brain damage and died of lidocaine toxicity**
- **Off-site physician “medical director” did not examine patients, take their medical histories, or write individual prescriptions for the anesthetic gel**
- **Physician lost his license for 6 months**

AMERICAN SOCIETY FOR DERMATOLOGIC SURGERY POSITION

- **Non-physicians:**
 - **Are not trained to diagnose skin diseases like skin cancer.**
 - **Are not fully trained to comprehensively evaluate the causes, types and symptoms of skin conditions related to aging and sun-damage.**
 - **Are ill-equipped to treat these skin disorders without direct medical supervision.**
 - **This can lead to inaccurate treatment and the potential for harm.**

ASDS POSITION

- **Under appropriate circumstances, certain cosmetic medical procedures can be delegated.**
- **However, only trained and licensed medical staff with direct, on-site supervision by a physician should perform these procedures.**
- **On-site physician supervision ensures the necessary responsiveness to questions and a greater likelihood that complications will be avoided.**

POLICY RECOMMENDATIONS FOR PATIENT SAFETY

- **Definition of the practice of medicine should include the affectation of living tissue, not just the treatment of illness and disease.**
- **Appropriately trained physicians should be on-site and immediately available during the performance of cosmetic medical procedures**
- **Medical records should be kept**
- **Initial examination should be done by a physician before first treatment to ensure patient is a good candidate for the procedure and that there are not any pre-existing conditions or contraindications present**
- **False and deceptive advertising should be prohibited**

RECOMMENDED LANGUAGE FOR FALSE & MISLEADING ADVERTISING

Any advertising for a cosmetic medical procedure should:

- **Identify the physician and surgeon performing or supervising treatment**
- **Include a statement that the supervising physician or surgeon is board certified or board eligible for an accredited board**
- **Identify the particular specialty or subspecialty for which the physician or surgeon has certification.**

DEFINITION OF COSMETIC MEDICAL PROCEDURE

A treatment or procedure that uses a biologic or synthetic material, chemical application, mechanical device, or displaced energy form of any kind if it alters or damages or is capable of altering or damaging living tissue to improve the patient's appearance or achieve an enhanced aesthetic result.

Such acts or procedures include, for example, the use of all lasers, light sources, microwave energy, chemical application, the injection or insertion of foreign or natural substances, or soft tissue augmentation.

DEFINITION OF SUPERVISION

Immediate supervision: Physician must be in the same room as the procedure is taking place

Direct supervision: Physician must be on-site and immediately available while the procedure is taking place

General supervision: Physician need not be on-site but must be available for direct communication by telephone

SAMPLE REGULATORY LANGUAGE

From Louisiana:

- **Lasers “whether used or applied for surgical, therapeutic or cosmetic purposes on human beings” constitutes the practice of medicine**
- **All treatments and procedures must be performed under the licensed physician’s direction and immediate personal supervision—i.e., where the physician is physically present on the premises and immediately available at all times that the non-physician is on duty and retains full responsibility**

SAMPLE REGULATORY LANGUAGE

From Mississippi:

- **The use of laser, pulsed light or similar devices, either for invasive or cosmetic procedures, is considered to be the practice of medicine in the state of Mississippi**
- **Therefore such use shall be limited to physicians and those directly supervised by physicians, such that a physician is on the premises and would be directly involved in the treatment if required.**

After all, there's a reason
they're called
“*Medical* Spas”