

## Cosmetic Procedures in Physicians' Offices: An Emerging Liability Issue

### INTRODUCTION

For the last decade cosmetic procedures in the United States have been in high demand. According to the American Society of Aesthetic Plastic Surgery, during the time period between 1997-2005, the number of nonsurgical cosmetic procedures increased by 726 percent.<sup>1</sup> A variety of new high-tech products and devices are being aggressively promoted in the medical marketplace, further expanding existing treatment options.<sup>2,3</sup> In response to this trend, a growing number of physicians are considering the inclusion of cosmetic services in their traditional practices, and are making inquiries about specific terms and conditions that apply to this trade. While appearing to be simple and profitable, cosmetic services do have liability risks associated with them, especially when performed by providers who may treat patients without receiving adequate training or supervision.<sup>4, 5,6</sup>

Patients opting for elective cosmetic procedures have high expectations from treatment and a poor result may cause disappointment and emotional distress. This distress may be heightened by the fact that patients typically pay for such services out of pocket, which may make them more likely to initiate a negligence claim.<sup>7</sup>

Articles published in both the lay press and the current medical literature reveal the following areas of potential risk exposure:<sup>2,5,6</sup>

- Inadequate knowledge and/or skills
- Poor supervision of nonphysicians performing services
- Off-label use of medical devices and products
- Inappropriate selection of patients
- Misleading advertising

- Poor communication with patients regarding possible unintended results and complications of treatment

This *ClaimsRx* presents key professional liability issues and risk management considerations for physicians who are thinking of adding (or who have already added) cosmetic services to their practices.

### The Five Most Common Nonsurgical Cosmetic Procedures in 2005

Botox®	3,294,782
Laser hair removal	1,566,909
Hyaluronic acids (Hylaform™, Restylane™)	1,194,222
Microdermabrasion	1,023,931
Chemical Peels	556,172

Source: Cosmetic Surgery Quick Facts: 2005 ASAPS Statistics. January 3, 2006. Available at: [www.smartplasticsurgery.com/surgery/statistics.html#2005SURGICAL](http://www.smartplasticsurgery.com/surgery/statistics.html#2005SURGICAL). Accessed: 8/19/2006.

### Provider Training

Recent advances in technology have introduced a new generation of high-tech cosmetic products and devices to the health market. Physicians and allied health providers who utilize these products and devices are urged to obtain the highest level of available training and certification. Complications as serious as death have been reported due to improper use of lasers, light sources and radiofrequency devices, and numerous malpractice allegations have been made against physicians who perform cosmetic treatment.<sup>6</sup>

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The Food and Drug Administration's (FDA) approval of a medical laser device does not guarantee a safe cosmetic procedure. Laser devices should be selected based on the specific presenting disease or condition. Aggressive laser treatment may cause permanent scarring and changes in skin pigmentation which can take weeks or even months to manifest. When this happens, expensive corrective treatment may be required to make these complications less noticeable. Attention to patient complaints or skin alterations during a cosmetic laser procedure and immediate termination of the treatment process may reduce the risk of subsequent problems for patients and providers alike.

Patients' individual characteristics (e.g. age or skin color) can contraindicate certain cosmetic treatments. Obtaining a complete medical history and physical evaluation of a patient are critical to making this determination. Benign-looking moles, warts or other skin growths may require additional analysis and/or a specialist consultation to avoid potential allegations of failure to diagnose.

A continuum of care—from the initial evaluation of the patient to the treatment itself to follow-up care—is vital for achieving positive outcomes, including good physician-patient rapport and avoidance of professional liability exposure. Physicians and allied health providers performing cosmetic procedures are recommended to acquire necessary training regarding each of these care components.

Continuing medical education (CME) opportunities, clinical guidelines, practical workshops, short-term training courses and fellowships in cosmetic services are available to improve knowledge and skills of cosmetic service providers, including those offered by the American Academy of Family Physicians (AAFP) and American Society of Cosmetic Dermatology and Aesthetic Surgery (ASCDAS). Additionally, some manufacturers offer manuals and on-site training for the proper utilization of their products and devices.

## Supervision of Nonphysicians

Cosmetic procedures performed by nonphysicians pose a major risk management concern. A recent member survey of the American Society for Dermatologic Surgery (ASDS) revealed that nearly 41 percent of responding dermatologists witnessed an increase in the number of patients seeking corrections after undergoing nonphysician administered treatment.<sup>8</sup>

Physician supervision of nonphysicians performing cosmetic services is important to assure quality of treatment and compliance to the standard of medical care. Just as it is wise to educate nonphysicians about potential risks and complications of cosmetic procedures, it is also sensible to develop policies and protocols for supervision. While developing such policies and protocols physicians might consider the following recommendations:

- Precisely outline roles and responsibilities of nonphysicians.
- Specify types of cosmetic procedures that nonphysicians are allowed to perform.
- Indicate requirements for appropriate training and certifications.
- Describe possible risks and complications of cosmetic procedures.
- Develop specific instructions for emergency situations.

The physical presence of physicians in the office is recommended to assure proper implementation of the above steps and to provide care as needed.

## Regulations

### California

The California Medical Board expressed its position on medical cosmetic practices in an October 2002 Action Report. The report also presented information on specific categories of nonphysicians that are allowed to use medical lasers, dermabrators, Botox<sup>®</sup> and other types of cosmetic treatment.<sup>4</sup> Per this report, “unlicensed medical assistants, licensed

vocational nurses, cosmetologists, electrologists or estheticians may not legally perform these [laser] treatments under any circumstance, nor may registered nurses or physician assistants perform them independently, without supervision.” For Botox® injections, “physicians... may direct licensed registered nurses, licensed vocational nurses or physician assistants to perform the injection under their supervision. No unlicensed person such as a medical assistant may inject Botox®.”

The Action Report is available at: [www.rn.ca.gov/practice/rns.htm](http://www.rn.ca.gov/practice/rns.htm). Accessed: 08/15/2006.

### Rhode Island

According to a policy statement on office-based esthetic procedures issued by the Rhode Island Board of Medical Licensure and Discipline, “these procedures may be performed by an appropriately trained non-physician working under the supervision and direction of a physician or other practitioner acting within his/her scope of practice.”<sup>9</sup> The statement also emphasizes the responsibility of a physician for supervising nonphysicians performing cosmetic procedures.

The policy statement is available at: [www.health.state.ri.us/hsr/bmld/positions.php](http://www.health.state.ri.us/hsr/bmld/positions.php). Accessed: 08/12/2006.

### Off-Label Use of Medical Devices and Medications

Medical products and medications are commonly used outside the scope of their originally intended clinical application as set forth by the manufacturer and the FDA. For example, Botox®, typically used for treatment of moderate to severe frown lines between the eyebrows, may also be used for upper lip wrinkles. Although off-label use of medications and devices is frequently determined to be within the standard of medical care, to minimize the risk of potential allegations and liability exposure physicians may choose to utilize a separate consent form that specifically addresses the off-label use. The informed consent process for off-label use may include the following points:<sup>10</sup>

- Disclosure that the off-label use of the product or device is not approved by either the manufacturer or the FDA
- The specific risks and benefits to the individual patient
- Benefits and disadvantages of alternative treatment/prescriptions

### Advertisement of Cosmetic Procedures

Physician advertising is becoming a common practice for attracting new patients in a competitive medical environment. Professional medical advertising is governed by the US Constitution and federal and state laws, including the First Amendment and California Business & Professional Code §651. These laws strictly prohibit “false, fraudulent, misleading, and deceptive advertisement.” The examples of these definitions include advertising medical practice under different medical specialties without having adequate training and skills, or creating false or unjustified consumers’ expectations of favorable results. Violation of Business & Professional Code §651 is a misdemeanor which may result in “revocation or suspension of license or other disciplinary action.”<sup>11</sup>

Consistent with the state laws are the California Medical Association’s (CMA) ethical guidelines on physician advertising which convey the idea that any advertising or publicity, regardless of format or content, should be true and not materially misleading.<sup>11</sup>

Medical professional societies and organizations may develop their principles of professional medical advertising. For example, the American Society for Dermatologic Surgery (ASDS) has developed ethical tenets of advertising which include the following principles:<sup>12</sup>

- Advertisements should not create false or unjustified expectations.
- Advertisements that claim the physician has unique skills and remedies must be true and capable of substantiation.

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- Photos should be representative of results in general, attained by the average patient and be of comparable quality so as not to mislead.
- Testimonials should similarly represent results of the average patient.
- Advertisements should be readily identifiable as such.

### Patient Selection: Communication of Risks and Complications

Cosmetic procedures, like any other treatment, are not appropriate for every patient. For Botox® injections, contraindications may include a history of reaction to botulinum toxin, preexisting motor neuron disease and infection at the injection site.<sup>13</sup>

Laser or intense pulsed light sources (IPLS) are effective methods to reduce excessive hair growth. Despite their increasing popularity, a number of side effects and complications are associated with these treatments including pigment alteration and scarring. In order to minimize the chances of poor outcome, the type of laser or IPLS and its specific parameters may be adapted to the individual patient with regards to his or her hair thickness, pigment concentration and Fitzpatrick skin type.<sup>14</sup>

Clinical guidelines and treatment protocols addressing proper selection of patients should be developed by medical practitioners to minimize the risk of poor treatment results and more closely meet patient expectations. Educational materials provided to patients will assist them in decision-making regarding proposed treatment options. The information about potential side effects and treatment complications should be discussed with a patient and included in the written informed consent form. The fact of such a discussion should be documented in the patient's medical record.

### Case Example # 1

#### *Allegation*

Negligent facial laser pulse treatment resulting

in hyper-pigmentation of treated areas in a 39-year-old female patient.

#### *The Event*

A 39-year-old female patient presented to a medical office for intense pulse light laser treatment of facial melasma/hyperpigmentation. The physician evaluated the patient and determined her to be Fitzpatrick Skin Type III (olive complexion that tanned easily).

A registered nurse performed the procedure. No complications or complaints were recorded during the procedure, and after receiving discharge instructions the patient went home.

Two months later the patient returned disappointed by the lack of desired results. She agreed to undergo a stronger treatment with the use of more aggressive treatment parameters. The same nurse performed the procedure again without apparent complications or side effects.

The following day the woman returned to the office with complaints of swollen eyes and red-ened areas across her nose, cheeks and chin. This time she was seen by the physician, who started her on a tapered prednisone regime. Over the next three weeks her condition improved considerably. However, she developed hyperpigmentation of the treatment areas around her nose and chin. The physician prescribed a facial cream containing vitamin A and advised the patient to return in one month for a follow-up visit. The patient neither returned nor answered phone calls from the office, and instead notified the physician about the intent to file a medical malpractice claim.

#### Case Analysis

Expert reviewers recognized the nurse's lack of training as the major problem in this case. At the time of the incident the nurse had been employed in the office only for a week. She did not receive formal training in cosmetic treatment, and did not have sufficient skills and knowledge to perform the procedure. Furthermore, the nurse had not read the manufacturer's manual and failed to notice a small

## The Effectiveness of Laser Treatment Depends on Many Factors, Including the Following:

- The selection of the correct device for a given treatment
- The training and skill of the person operating the device
- The wavelength of the beam of energy that targets the tissue
- The power settings used, duration of each energy pulse, amount of time between pulses, number of pulses per treatment and number of treatments administered
- The color of the skin and/or hair of the person being treated

Source: Cosmetic Laser Treatments. 2004 Jun 17. Medical News Today. 2006 Aug 25. Available at: [www.medicalnewstoday.com/medicalnews.php?newsid=9580](http://www.medicalnewstoday.com/medicalnews.php?newsid=9580). Accessed: 08/22/2006.

illuminated dot indicating overheating of the treatment device.

According to reviewers of the case, the risk of both hypo- and hyperpigmentation from the intense light procedure is higher for persons of darker complexion, such as this patient. Recognizing this as a higher-risk patient the physician should have supervised the nurse and should have paid more attention to the treatment procedure.

Although the patient signed an informed consent form to the effect of possible blistering or crusting of the treatment area resulting in permanent hypo- or hyperpigmentation, she did not recall any discussion with the physician or nurse about her chances of developing the complications. Neither was such a discussion documented in the patient's medical record.

### Cosmetic Laser Treatment

Cosmetic laser treatment is in demand for conditions including excessive hair growth, wrinkle reduction, acne scars, pigmented blemishes and vascular lesions. Cosmetic laser procedures, despite the apparent benefits for consumers, can result in serious side effects and complications. The examples of such complications include atrophic and hypertrophic scars, depigmentation and hypopigmentation of the skin, immediate pain, swelling and formation of

blisters or burns. According to the ASCDAS, misuse of laser devices and inappropriate laser parameters are the most common causes of laser treatment complications.<sup>15</sup>

### Case Example # 2

#### *Allegation*

Negligent intense pulse light treatment of facial telangiectasia (i.e., spider veins) resulting in hypopigmentation and scarring of treatment areas in a 48-year-old female patient.

#### *The Event*

A 48-year-old female patient presented to a medical office for intense pulse light treatment of facial telangiectasia. During the procedure the patient repeatedly complained of pain, though no skin color change or other side effects were recorded.

The following day the patient returned with complaints of swelling around her eyes, and oozing of the treated skin. After examining the patient, the physician advised her to wait for several weeks and that the damaged skin would "scab over" and heal.

In three months the woman returned complaining of slow recovery and residual facial indentations. The original physician was on temporary leave and she was seen by another physician. The second physician told the

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patient that the indentations could take up to one year to heal and, alternatively, suggested to treat them with collagen injections. The patient refused.

Approximately ten months later the patient was seen by a dermatologist. His exam revealed white papules on the patient's right cheek, a white scar with surrounding erythema on her left cheek, and a few shallow scars in the area of left nasal fold crease. The dermatologist told the patient that the scarring and areas of hypopigmentation were probably caused by aggressive laser treatment. Another dermatologist with whom the patient consulted expressed the same opinion. Both doctors told the woman that hypopigmentation and scarring were permanent, and suggested a series of expensive laser procedures to make them less noticeable.

### Case Analysis

Expert reviewers consulted for this case noted that more advanced devices were available in the market with improved technical capabilities for precision and power of intense light pulse treatment. According to these experts, the use of such devices would have been more appropriate in this case. Experts testified that the permanent hypopigmentation and scarring resulted from overheating the treatment area during the procedure. According to the experts, the treatment parameters were too aggressive for the patient's condition. These parameters were specified by the manufacturer when the physician bought the device. A year later, the manufacturer contacted all the consumers and advised them about revised parameters. However, the physician failed to remember receiving this information and claimed that she did not know about proposed changes in the parameters.

### Case Example # 3

#### *Allegation*

Failure to perform a biopsy of facial skin lesion resulted in delayed diagnosis of malignant melanoma in a 63-year-old male.

#### *The Event*

A 63-year-old male patient presented to his family practitioner with a complaint of multiple lesions on the right side of his face. According to the physician's notes most of the lesions had slightly elevated, defined borders, were light brown in color, and varied in size, ranging between 3mm-6mm in diameter. A few of the lesions had flat, irregular borders. The physician diagnosed lesions as seborrheic keratoses and offered to remove them using laser technology. The physician mentioned the procedure to be "very safe" and the patient signed a consent form. According to the physician's notes, the patient tolerated the treatment well and had an "excellent result." No discharge instructions were given to the patient and no follow-up visit was scheduled.

Two months later the patient noticed a growth on the right side of his face which progressively grew and occasionally bled. The growth did not seem dangerous to the patient and he waited for seven months before he consulted with a dermatologist. The dermatologist performed a biopsy of the growth, which was diagnosed as malignant melanoma, Stage IV.

### Case Analysis

According to expert reviewers, a diagnosis of seborrheic keratoses is usually made based on its clinical presentation. The reviewers testified that the color of the lesion, border contours and size are essential elements for diagnostic evaluation. In atypical cases, seborrheic keratoses may resemble malignant melanoma, which has more flat and irregular borders. Utilization of additional diagnostic methods and tools may be needed to avoid delay in diagnosis and potential allegations of negligent medical care. The experts opined that the physician should have performed biopsy of the lesions and should have referred the patient to a specialist (i.e., dermatologist) before arriving at a diagnostic conclusion.

Although the patient signed the informed consent form, he claimed the physician did not discuss with him the risks and benefits of the

treatment. The physician failed to record the fact of such a discussion in the patient's medical chart. Moreover, no discharge instructions were given to the patient, and neither was any attempt made to schedule the patient for a follow-up visit.

## Summary of Risk Management Recommendations

- Obtain necessary skills and knowledge prior to performing cosmetic procedures. Investigate available training courses and opportunities.
- Refer to clinical guidelines and treatment protocols for appropriate selection of patients. With each patient, discuss their individual risk for developing potential treatment complications.
- Pursue suspicious or incidental findings (e.g., moles or skin growths) to diagnostic resolution.
- Comply with state-specific regulations pertaining to nonphysician performance of medical cosmetic services. Develop policies and protocols for supervision of nonphysicians performing such services.
- Utilize a separate consent form for off-label use of cosmetic products and devices. Inform patients when a proposed use of a particular medical product or device is outside the clinical indications defined by the FDA and manufacturer.

- Adhere to ethical norms of advertising. Do not make false, fraudulent or misleading claims in advertising.
- Contact NORCAL's Underwriting Department before expanding your practice to include cosmetic services to ensure approval of coverage.

## CONCLUSION

A growing number of medical practitioners are expanding the realm of their traditional practices to include cosmetic procedures. Serious side effects and treatment complications may occur when cosmetic services are performed by providers without adequate skills and knowledge. Poor outcomes can lead to increased liability exposure, but this exposure can be mitigated through prudent risk management-based practices. Maintaining high standards with regard to training and skill development of both physicians and nonphysicians who perform cosmetic services is of the utmost importance. Physicians are encouraged to develop standardized policies and procedures, sharpen their supervision of nonphysicians, enhance their communication with patients (including proper patient selection and thorough informed consent), and maintain meticulous medical records. Implementing these strategies may reduce the likelihood of being named in a malpractice allegation, as well as help defend a claim if it does occur. ■

### Notes

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