

# OMICDIGEST

Ophthalmic Risk Management Digest

## MESSAGE FROM THE CHAIRMAN



**No area of ophthalmology** is more controversial and difficult to underwrite than oculoplastic and oculofacial procedures. For this reason, OMIC has always had an oculoplastic specialist involved in making coverage decisions on what I will refer to here as "cosmetic" procedures. This includes past

Underwriting Committee chair, Michael J. Hawes, MD. Additionally, OMIC has maintained an ongoing educational cooperative venture with the American Society of Ophthalmic Plastic and Reconstructive Surgery since 1998. Thus, we feel very confident in our ability to assess the liability risks of ophthalmologists who perform cosmetic procedures and to establish the underwriting guidelines and requirements to minimize these risks. We believe it is because of these guidelines that we have a record of low frequency and severity of cosmetic surgery related claims.

Historically, these procedures were usually performed by oculoplastic specialists on established patients in a medical office or surgery center. With storefront medical spas now cropping up in malls and on street corners, patients can walk in and have laser hair removal,

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## Facials, Fillers, and Physicians: Keeping the "Medi" in Medi-Spa

By Betsy Kelley  
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**U**ndercover officers in Florida find an unlicensed cosmetologist injecting Restylane and another unlicensed individual performing sclerotherapy at a medical spa. The patients are not seen by a physician, nor are medical exams conducted. The cosmetologist is arrested for the unlicensed practice of medicine and possession of legend drugs with intent to dispense. The medical director is disciplined by the medical board, including a letter of concern, fine, and mandatory community service.<sup>1</sup>

Another doctor takes over as medical director of a North Carolina medical spa. Before reviewing the spa's policies and practices, he authorizes the compounding pharmacy to continue supplying a numbing gel used with laser hair removal. Within one month of the doctor's hiring, a 22-year-old college student dies of poisoning after using the lidocaine she had received from the pharmacy in anticipation of her treatment. The medical director's license is suspended for six months for failing to ensure that the prescription gel was properly dispensed.<sup>2</sup> The former medical director is also charged with unprofessional conduct for setting up the protocols that allowed the clinic to dispense the gel without individual prescriptions and for failing to train staff in its use.<sup>3</sup> The resulting wrongful death lawsuit from this case settles for policy limits against each of the multiple defendants.

These publicized incidents illustrate some of the risks physicians take when they establish or agree to serve as medical directors or supervising or prescribing physicians for a medical spa. Physicians must educate themselves about the risks associated with these facilities in order to reduce their likelihood of liability claims, licensure actions, or other adverse consequences. By understanding and addressing these exposures, physicians can not only better protect themselves but also improve patient safety.

Now is the best time to act on this issue. Medical spas are the fastest-growing segment of the spa industry, increasing from 400 medical spas in the United States in 2004 to more than 2,000 by 2007.<sup>4</sup> This number will continue to rise. While fewer patients are seeking elective surgery as a result of the economic downturn, many are turning to less expensive substitutes. Patients who previously would have undergone a facelift are now more likely

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# Facials, Fillers, and Physicians

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to select skin resurfacing procedures, injections of fillers or Botox, or chemical peels as a more cost-effective alternative. And the lower cost of obtaining these services from non-physician personnel makes medical spas even more attractive. It's not only patients who are drawn to medi-spas; seeking ways to supplement their declining revenues, some physicians may feel compelled to set up or expand their own medical spa business.

## What is a Medical Spa?

A medical spa is a facility that provides a variety of aesthetic medical procedures and traditional spa therapies under the supervision of a physician, generally in a spa-like setting. The spa may be located within a physician's office, within the physician's medical building, or in a stand-alone setting. Medical spas may be physician-owned, or depending upon—or in violation of—state laws and regulations, they may be owned by entrepreneurs or franchises. Typically, services are rendered by aestheticians, nurses, or other allied health care professionals under the supervision of a physician who may or may not be on site.

## Know the Laws

Although many states do not specifically regulate medical spas, all facilities where medical care is rendered are subject to the same laws and regulations as health care facilities, including those pertaining to corporate ownership and scope of practice. Corporate practice-of-medicine laws determine who must own or supervise the practice, and regulatory boards establish to whom certain activities can be delegated and under what circumstances. Some states may also require that the facility be licensed or certified by the state in which it operates. Other regulations may dictate facility and equipment requirements such as water, restroom, and health and safety requirements. Nonetheless, experts opine that most medical spas today operate in ignorance or violation of these laws and regulations.

Even well-intentioned, law-abiding physicians find scope-of-practice laws complex and confusing, in part because scopes of practice vary widely. Obviously, scope of practice varies among types of licensees within a given state. Physicians moving to a different state may not expect significant differences from state to state for a specific type of licensed practitioner. To make matters worse, different agencies within the same state may take opposing positions. For example, according to the Alabama Board of Cosmetology, a cosmetologist or aesthetician can inject Botox and dermal fillers under the supervision of an on-site physician. However, that state's medical board has ruled that cosmetic injections are the practice of medicine and must be performed by a licensed physician. Therefore, while it appears that an Alabama cosmetologist who performs such services under the direction and supervision of a physician would not be sanctioned by his or her licensing board, the supervising physician could be charged with unprofessional conduct and be subject to disciplinary action. When conflicts such as these exist, it would be prudent for the physician to adhere to the most restrictive regulations (see the **Hotline** for recommendations on how to safely make delegation decisions).

To protect public safety, and provide guidance to practitioners, regulatory boards in some states have established policies clearly defining their position. For instance, several nursing boards have developed policy statements or protocol guidelines regarding aesthetic cosmetic procedures. Other state boards make determinations on a patient-by-patient basis, or provide advice specific to each provider based upon the provider's training, skills, and experience. Some counsel nursing staff to follow a decision model to determine whether a particular procedure falls within their legal scope of practice. Others indicate that

scope of practice determinations will not be made until or unless a complaint against the provider has been filed and even then will depend upon the specific facts of the case.

Managing scope of practice issues is even more complex when one considers that regulations are continually in a state of flux, and new regulations that expand or restrict scope of practice can be passed at any time. Ignorance of local, state, and federal laws and regulations, however, is not an acceptable defense, and failure to abide by them can result in fines, other disciplinary action, or suspension or revocation of licensure. Therefore, it is important for physicians who associate themselves with a medical spa to personally research the applicable requirements and to ensure that the facility is in full compliance. Consult with each of the nursing, cosmetology, physician, and other professional boards as applicable in your state for final governance rules. Establish a policy to review scope of practice laws on a routine basis, perhaps annually or biannually.

## Supervision Required

By definition, medical care is part of the practice of medicine, and must be provided by or under a physician's supervision. This is true regardless of where the care is provided. Thus, while many medical services provided at medical spas can legally be performed by certain types of qualified non-physician personnel, the supervising physician's role must be evident. First, the physician must generally prescribe or order medical treatments (see the **Hotline** for assistance in distinguishing medical treatments that need a physician's order from cosmetic procedures). In some situations, the physician may also be required to assess and evaluate the patient before ordering the treatment. Ultimately, the supervising physician is responsible for the patient and could be held liable for any legal/regulatory violations and patient injuries that occur.

Before procedures can be delegated to non-physician personnel, the supervising physician has a duty to assess the health care provider's qualifications. The physician should have direct knowledge of each individual's licensure, training, certification status, knowledge, and experience in each procedure the provider will perform. In addition, the physician should verify that the procedure falls within the provider's legal scope of practice (licensed staff) or services (unlicensed assistive personnel). No procedure should be delegated to a provider who has not satisfactorily demonstrated current competency in the necessary skills.

In order to adequately supervise the health care providers, the supervising physician must also be competent in each procedure that is performed at the medical spa. Many states have passed laws or regulations stipulating that the supervising physician have the knowledge, skill, and ability to personally perform each procedure. Some states further require that the physician actively perform such procedures in his or her practice.

The minimum level of supervision legally required while the treatment is being rendered varies from state to state and also depends upon the professional designation of the provider who will render services. In some situations, the physician may be required to be in the same room at the time services are rendered; in others, it may be acceptable for the doctor to be elsewhere in the building. In the case of licensed health care providers, the regulatory board may allow the physician to be "readily available," to be physically available within a specified time frame, or to simply be available by telephone. To increase patient safety, minimize liability exposure, and reduce the possibility of disciplinary action for failing to properly supervise non-physician staff, a qualified physician should be available on site whenever medical services are performed. In addition, the supervising physician

should routinely review, date, and sign the medical records. Written protocols clarifying the role and responsibilities of the physician and of non-physician employees will aid in the appropriate delegation of services. Such protocols also provide supporting documentation of the supervision extended should a complaint be filed.

### **Treat Medical Procedures as Medical Procedures**

Members of the public often believe that procedures rendered at medical spas are cosmetic services with guaranteed results rather than medical procedures with risks; they are misled both by having the services provided by non-physician personnel in non-clinical settings and by brochures and advertisements. It is not surprising, then, that patients often fail to understand the risks involved, have unrealistic expectations, and become dissatisfied if complications or side effects occur.

Clients should be treated as patients, and treatments should be handled as the medical procedures they are, regardless of whether services are rendered in a spa or clinical setting, or performed by a physician or allied health care provider. Practically speaking, this means that HIPAA regulations are respected, and a qualified health care provider or physician obtains and documents a medical and medication history and performs a physical examination of each patient before a physician orders treatment. As with any other medical procedure, an informed consent discussion is held with each patient prior to treatment and the patient signs a consent form documenting understanding of the treatment goals and risks. Medical records are maintained that document the initial assessment, course of treatment, informed consent, and postoperative care rendered.

Just as in hospitals, surgery centers, and physician offices, medi-spa facilities and staff would be wise to expect and be prepared for the

unexpected. While uncommon, serious medical complications and emergent conditions may arise coincident to or as a result of the procedure. Patients have suffered serious burns from laser procedures performed at medical spas and life-threatening allergic reactions to medications. Supply the medical spa with the medical personnel and equipment necessary to monitor patients and deal with any potential complications that may occur. To ensure that patients can obtain prompt emergency care, establish a written transfer agreement with the nearest acute care hospital and train staff on how to respond to an emergency.

Medical spas represent a new source of liability exposure, but the informed physician can minimize risk and improve patient safety by complying with scope of practice and other laws and regulations, providing the appropriate level of supervision, and recognizing that the services rendered are medical procedures subject to the same guiding principles as other medical services.

1. State of Florida Department of Health, DOH Case No. 2007-08728.
2. Avery S. "N.C. board suspends spa doctor." *The News & Observer*, September 9, 2005. Retrieved April 21, 2009 from [http://www.newsobserver.com/news/health\\_science/medical\\_spas/story/332572.html](http://www.newsobserver.com/news/health_science/medical_spas/story/332572.html).
3. Shimron Y. "Doctor linked to numbing-gel death reaches deal." *The News & Observer*, August 16, 2007. Retrieved April 21, 2009 from [http://www.newsobserver.com/news/health\\_science/medical\\_spas/story/672197.html](http://www.newsobserver.com/news/health_science/medical_spas/story/672197.html).
4. "Deadly Beauty Treatments." *In Prevention*, March 8, 2007. Retrieved April 21, 2009 from [http://www.prevention.com/cda/article/deadly-beauty-treatments/46d268f271903110VgnVCM10000013281eac\\_\\_\\_/lifelong.beauty/anti.aging.arsenal/cosmetic.procedures](http://www.prevention.com/cda/article/deadly-beauty-treatments/46d268f271903110VgnVCM10000013281eac___/lifelong.beauty/anti.aging.arsenal/cosmetic.procedures).

Contact the following resources for additional information about medical spas:

The International Medical Spa Association, [www.medicalspaassociation.org](http://www.medicalspaassociation.org).

"The Bottom Line: The Business of Medicine—Medical Spas," Medical Board of California, [http://www.medbd.ca.gov/licensee/medical\\_spas-business.pdf](http://www.medbd.ca.gov/licensee/medical_spas-business.pdf).