The Medical Spa Movement and Regulatory Uncertainty

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Few things in the regulation of health care professionals and entities bring the same level of emotion and turmoil as scope of practice battles. Some of the latest firing lines – i.e. staffing at freestanding emergency rooms, redi-clinics, and medical spas – involve face offs between not just physicians and non-physicians, but also between various groups of physicians.

Medical Spa Overview

Medical spas are one of the fastest-growing segments of the spa industry with nearly 2,500 nationwide as compared with 500 in 2004.¹ They generate billions in revenue annually, and often involving a number of different professionals including physicians, cosmetologists, electrologists, aestheticians, and nurses.² Competition among these professionals for customers seeking the services and procedures provided by medical spas can be intense and often pit medically-trained individuals, who are licensed by the state against unlicensed individuals performing arguably medical procedures.

The preferred business model and practice for medical spas is for a spa owner to form an alliance with a physician in order to obtain FDA-regulated devices and pharmaceuticals.³ The physician then remains offsite and delegates the cosmetic procedures to non-physicians to administer to those seeking the services.⁴ This practice is not legal in all states, but the model generally describes the structure where a non-physician performs the procedures.⁵ The lack of direct physician oversight is converse to the model recommended by the International Medical Spa Association, a New Jersey trade group, which defines a medical spa as follows:

[a] medical spa is a facility that operates under the full-time, on-site supervision of a licensed health care professional. The facility operates within the scope of practice of its staff, and offers traditional, complementary, and alternative health practices and treatments in a spa-like setting. Practitioners working within a medical spa will be governed by their appropriate licensing board, if licensure is required.⁶

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³ Andrew D. Swain, The Hidden Dangers of ‘Medical’ Spas, 45 TRIAL 40, 40 (May 2009).
⁴ Id.
⁵ Id.
As a result of the increasing number of non-physicians administering topical anesthetics to individuals, or using lasers to remove tattoos or skin blotches, consumers are at an increased risk of complications – and states are turning their attention towards regulating the spas.

Consumers’ Adverse Results and Complications

In the soothing atmosphere of a medical spa, with its soft background music and dimly-lit rooms, the idea of risk and complications to an individual resulting from laser hair removal, Botox® injections, or chemical peels would seem unlikely. However, the data being released by the medical community suggests otherwise. The FDA has reported two deaths related to the misuse of topical anesthetics in connection with laser hair removal procedures, and recently issued a Public Health Advisory statement for the medications.

The FDA’s statement noted that when topical anesthetics are applied to the skin surface, “they can be absorbed into the blood stream and, if used improperly, may cause life-threatening side effects, such as irregular heartbeat, seizures, breathing difficulties, coma, or even death.” Even injectable drugs to remove wrinkles such as Botox® have been known to cause complications and even death. Temporary adverse reactions resulting from improperly-performed spa treatments include pain, swelling, redness, discoloration of the skin, and blistering.

Though serious complications and fatalities are not the norm, the number of patients seeking medical attention due to poorly-performed spa procedures has increased. Further, medical associations have issued warnings to patients about the risks of receiving low-cost cosmetic procedures performed in a non-medical setting. The end result is that more states are looking to place increased restrictions on medical spas and those who perform the procedures.

The Scope of Practice Battle

Medical spas raise several regulatory questions. At the heart of the matter is defining the line between the practice of medicine and the practice of cosmetology and aestheticians.

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7 Swain, supra note 3, at 40 (citing Diane Gorgos, Dermatology Nursing News: Lidocaine-Induced Deaths Raise Questions about Med-spa Management, 17 DERMATOLOGY NURSING 389, 390 (Oct. 2005)).
9 Id.
11 Swain, supra note 3, at 40-41.
12 Id. at 41. An American Society for Dermatologic Surgery (ASDS) survey in 2007 reported that 56 percent of responding physicians “indicated that there had been an increase in the number of patients they had treated as the result of complications caused by a non-physician.”
13 Id.
In most state, cosmetology involves a licensed individual, among other things, treating hair using coloring or bleaching solutions, treating a person’s facial skin using creams or lotions, and offering manicure or pedicure services. Aestheticians are licensed skincare specialists who treat facial skin often disfigured or affected by medical trauma or medical procedure.

If laser hair removal is a non-medical cosmetic procedure, then allowing a licensed cosmetologist or technician to perform the service would be relatively non-controversial. If there were an agreement that procedures such as laser hair removal involve the practice of medicine, the debate would then hinge on the exact level of involvement needed from a physician in terms of supervision and/or delegation. There is, however, no agreement on which procedures offered by medical spas are in fact medical and which are not.

Dermatologists and plastic surgeons generally state that the procedures are medical in nature and therefore a high level of physician involvement is required. They cite cases of burns and improperly-performed procedures that have lead to a 41 percent rise in botched treatments. The other side largely consists of technicians, cosmetologists, and aestheticians who have been performing similar services for years and primary care physicians who have turned to the medical spa industry and its attractive all private pay clients. They argue that many of the personnel at medical spas have more experience and more training on lasers and similar devices than the physicians who argue they should have exclusive rights to use them.

State Legislatures and regulatory boards are slowly coming to look at this issue. The Federation of State Medical Boards conducted a 50-state survey on laser use and delegation by physicians that covers the relevant state laws on many medical spa procedures. Even a quick review of the chart shows the broad disparity in regulatory schemes on this issue. Some states have long, detailed provisions while others have none at all. One organization for laser and medical aesthetics has stated, “[a]lthough laser certification is a natural and profitable component to an aesthetician’s training repertoire, anyone can become a certified laser technician—soccer moms, secretaries, sales professionals, teachers, and more.”

It is important to note that lasers and intense pulsed light devices used for hair removal and other cosmetic procedures are classified as Class II medical lasers by the FDA, and thus deemed a prescription device, which, according to federal regulations “is not safe except under the supervision of a practitioner licensed by law to direct the use of such

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14 See Texas Dep’t of Lic. and Reg., Cosmetology Law, available at http://www.license.state.tx.us/cosmet/cosmetlaw.htm#001 (last visited June 8, 2009).
device, and ... is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.'

Regardless of the presence of state regulation of medical spas, the supervising physician is ultimately responsible for overseeing patient care, for determining who is qualified to perform the procedures, and for determining the degree of supervision that is required.

**State Regulation of Medical Spas**

The Florida Legislature enacted regulations in 2006 limiting the number of satellite offices that one physician could supervise, the distance of each from the doctor’s main office, and other patient safety measures relating to cosmetic procedures.

New Jersey, a state that has long recognized the use of lasers as a medical procedure, allows only doctors licensed by the state board of medical examiners to use medical lasers for cosmetic purposes, and physicians may not delegate the procedures to non-physicians.

Following Florida’s lead, a state task force in the Commonwealth of Massachusetts issued a comprehensive 37-page proposal that recommended medical spas be licensed by the state Department of Public Health, suggested the implementation of a classification system for medical aesthetic procedures and those qualified to perform them, and requiring individuals performing medical spa procedures to be licensed by an appropriate Board of Registration. Based upon the recommendations of the task force, further legislative action involving medical spa regulation is expected to continue in the state.

**Conclusion**

It is likely that the scope of practice debate will only increase in the coming months regarding the appropriate amount of state regulation of medical spas. Until a solid statutory scheme is in place in a state demarcating the lines of the practice of medicine and procedures allowable by a non-physician, the lines will continue to be blurred.


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20 Swain, *supra* note 3, at 41.
22 Id. (citing N.J. Admin. Code § 13:35-4A.12(d) (2009)).