



By Andrea Nadai

## LEGAL ISSUES

# Are We There Yet?

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Do you have a plan in place for keeping up with the inevitable changes in state regulations governing who can perform services using light-based devices?

The medical spa industry has experienced exponential growth since its inception in 1999. According to the International Spa Association ([experienceispa.com](http://experienceispa.com)), there were 976 medical spas operating in 2007, a 7% increase from the previous year, with revenues exceeding \$1 billion. A 2006 analysis by the American Academy of Facial Plastic and Reconstructive Surgery ([aafprs.org](http://aafprs.org)) revealed that the number of women undergoing nonsurgical cosmetic procedures is up by 69% since 2000. The antiaging movement and availability of new products and treatments continue to fuel this growth. Laser and intense-pulsed-light (IPL) treatments for photorejuvenation, and neurotoxin and dermal filler injections are frequently the cornerstones of medical spa services. As more physicians and entrepreneurs enter this industry, it is important to understand current developments in the regulation of medical spas and the treatments they provide.

Regulation of aesthetic medical treatments is directed by individual states. Each state has its own definition of what constitutes the practice of medicine and whether medical procedures may be delegated to non-physicians. Currently there is no generally accepted definition for "medical spa." However, the key element among all definitions is the need for a physician as the medical director. With this in

mind, medical spa owners need to be informed of changes that state medical boards and other professional boards are making to laws and regulations governing these procedures.

### Changing Regulatory Landscape

Seventy percent of state medical boards consider the use of light-based devices as the practice of medicine. A comprehensive survey conducted in all 50 states revealed that, although there is consensus that these procedures require the oversight of a physician, delegation practices vary widely. At one end of the regulatory spectrum, state regulations permit only physicians to perform light-based procedures. At the other end, physicians in some states can delegate some procedures to individuals without any kind of medical licensing. The majority of states (34) permit some form of delegation, most often to licensed professionals or allied health providers. State regulators are paying increased attention to delegation practices in medical spas. In 2005, the American Society for Dermatologic Surgery ([asds.net](http://asds.net)) launched a patient safety campaign in response to a rise in complications seen by dermatologists from cosmetic procedures performed by non-physicians. Based on safety concerns identified by consumers and practitioners, states are studying the matter closely with an eye toward more regulation. A number of states currently have pending matters ranging from changes in state law to developing professional board practice opinions. The following examples illustrate a variety of regulatory paths recently taken by legislators and professional boards in different states.

Illinois and New York are among the states considering statutes that address delegation of light-based procedures. Illinois *House Bill 3679* amends the Medical Practice Act. It allows a physician to delegate the operation of a laser or IPL system for the purpose of epilation, photorejuvenation, or other nonmedical cosmetic procedures to a physician assistant,



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advanced practice nurse, registered nurse, electrologist or other licensed personnel. The bill does not contain language related to level of supervision required. It was referred to the House Rules Committee on January 10, 2008.

New York has introduced legislation to prevent the unsupervised use of Class IIIB and IV lasers, IPL systems, radiofrequency and medical microwave devices in spas and other "skin clinics." *Assembly Bill 8142* identifies the use of such devices as the practice

of medicine and limits practitioners to physicians, nurse practitioners, dentists and podiatrists. Physicians may delegate these procedures to nurses only when direct supervision is provided. The bill is currently being reviewed by the Higher Education Committee.

In February 2008, the **Kentucky** Board of Nursing adopted an advisory opinion related to the performance of cosmetic and dermatological procedures. The advisory opinion identifies the procedures that registered and licensed practical nurses may perform and the level of supervision they require. The advisory opinion also defines criteria related to training, written protocols and competency assessments.

The **North Carolina** Board of Cosmetology implemented new rules that prohibit cosmetologists, estheticians and manicurists from using FDA-rated Class III devices. Effective January 1, 2008, the regulations do permit these professionals to use Class II devices under the direct supervision of a licensed physician.

### Task Forces

**Massachusetts** is among the first states to tackle the regulation of medical spas head-on. In November 2006, it formed a Medical Spa Task Force, consisting of physicians, nurses, estheticians and electrologists. The group has evaluated the various aesthetic procedures on the market today and is developing recommendations concerning the qualifications required of a person performing these procedures, the training requirements for providers and the regulations that govern the operation of medical spas. The findings of the task force will be considered by the state legislature later this year. This coordinated approach to regulating a single entity with input from a consortium of state agencies and professional boards is groundbreaking and may become a model for other states.

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In August 2007, the **California** Boards of Medicine and Nursing convened a joint task force to study safety issues related to the use of laser and IPL devices by physicians, nurses and physician assistants. The task force is charged with identifying

the level of supervision needed for elective cosmetic procedures and the level of training necessary to ensure competency. It will also establish guidelines for standardized procedures and protocols. The deadline set for the task force is January 2009.

### Enforcement

State regulators are keeping a close eye on medical spas. Aside from loss of licensure, some states may impose civil and/or monetary penalties on those who do not adhere to the board statutes and regulations. Recently, two **Florida** laser clinic owners were arrested on misdemeanor and felony charges for operating their clinics without the supervision of a physician—a violation of state law. One of the clinic owners stated she was unaware she was breaking the law. The take-home message is that medical spa operators must stay abreast of the ever-changing regulatory landscape or risk the consequences.

Based on the surge of state regulatory activities in recent years, it is clear that more changes are on the horizon. Due to patient safety concerns, it is likely that states will continue to address delivery of medical spa services through new legislation, regulations or advisory opinions. Researching state and federal regulations can be an onerous task, consuming significant time and requiring specific experience. Since ignoring the laws and rules could lead to costly outcomes, more providers are retaining knowledgeable legal counsel or seeking information from one of the consulting companies that specialize in this area. Set your strategy for keeping up with changes in your state. ▣

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