BUSINESS CONSULT

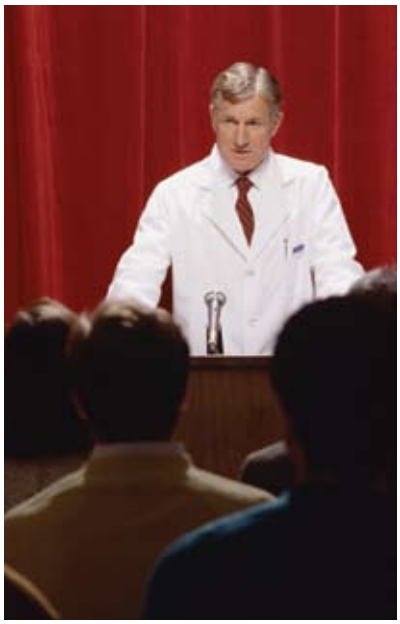
Medical Spa Regulations

By Andrea Nadai, MHP

The Massachusetts Legislature convened a task force to draft standards and regulations for medical spas. Its findings may serve as a model for other states.

State officials across the nation are struggling to address the need for appropriate regulations governing the use of laser and light technologies in medical practices, laser centers and medical spas. In 2006, the Massachusetts Legislature called upon the Board of Medicine to convene a task force to study and draft standards and regulations regarding medical spas and their use of laser and intense pulsed light devices, microdermabrasion techniques, chemical peels, soft tissue fillers, sclerotherapy, botulinum toxin injections, and other related procedures. This article provides an overview of the Massachusetts Medical Spa Task Force and the steps it has taken to evaluate state regulation of medical spas. The task force represents a consortium of state agencies and professional boards, including:

One goal of the task force was to assure appropriate supervision of medical spa procedures.



- Representatives from the Boards of Medicine, Nursing and Cosmetology.
- Two ranking members from the state Legislature (one from the House and one from the Senate) with experience in the public health sector.
- Four physicians—one internist, one plastic surgeon and two dermatologists.
- One nurse.
- One registered electrologist.
- One consumer.

All licensed professionals appointed to the task force had significant experience with light-based devices.

From the start, the task force charted a course that could be considered groundbreaking in other states. Their overall objective was to establish recommendations that were in the public's interest, even if they were beyond the scope of the individual boards' current operations. This approach took entities accustomed to working solely within their own practice area and transformed them into a collaborative work group. Task force members were encouraged to look beyond individual board practices and consider information presented by colleagues and experts when determining what would be best for the public. They were instructed not to constrain their recommendations due to current statute and/or regulations. The Legislature considered it appropriate for the task force to include proposals for statutory changes if it found that the current regulatory environment failed to include adequate consumer protection related to medical spa services.

Setting The Framework

The Medical Spa Task Force began its review by gathering information on current regulations, practices and safety concerns. They examined relevant regulatory practices in other states, reviewed relevant national standards and identified types of devices used and procedures currently performed in medical spas. Representatives from the Boards of Medicine, Nursing, Cosmetology and Electrology provided overviews of permitted practices and related education and training requirements. Industry representatives provided input on the medical

Photos.com

spa marketplace and the training of estheticians. Finally, concerns related to patient safety were identified by a physician from a leading dermatological association and a 2007 survey of American Society for Dermatologic Surgery members, which reported a steady increase in complications caused by non-physicians performing aesthetic procedures over the past five years.

The task force next worked to develop a regulatory framework based on the information gathered. Three questions emerged as focal points for the proposed regulations:

- Who should perform medical spa services?
- What services should be offered and how should they be regulated?
- In what environment should these services be provided?

A three-tier classification system was developed with consideration given to level of risk, type of supervision needed and training requirements. Level I procedures are noninvasive and demonstrate the lowest level of risk. LED therapy and microdermabrasion are examples of procedures included in this level. Since Level I procedures are not considered the practice of medicine, they are overseen solely by the Board of Cosmetology. Level II procedures represent a moderate level of risk and include nonablative and nonvaporizing lasers, intense pulsed light devices and radiofrequency devices. The highest level of risk is found in Level III, which includes ablative and vaporizing devices, chemical peels and the use of injectables. Procedures performed using Level III devices can only be administered by a physician. Facilities providing Level II and III procedures would require a medical spa license.

One goal of the task force was to assure appropriate supervision of medical spa procedures. Existing regulations permit physicians to act as medical directors even when they know little about aesthetic procedures and spend little time providing oversight to spa personnel. Proposed regulations concerning supervision and training aim to put an end to these practices. Medical directors and personnel providing medical spa services must meet certain licensure and training requirements. On-site supervision by a qualified healthcare provider would be required for Level II and III procedures. While the medical director is not always required to be onsite to oversee delegated procedures, he or she must be located within four hours of the medical spa and be present on-site 10% of the time each month for each site supervised. The task force relied on national standards in the development of its recommendations.

The task force also grappled with the issues of ownership and future oversight. It was determined that anyone can own a medical spa as long as appropriate medical personnel are hired for clinical supervision. The Department of Public Health would be responsible for licensing and inspecting medical spa facilities, while individual licensing boards would have jurisdiction over appropriate practices by their licensees. Since the field of medical aesthetics is constantly changing, it was determined that a separate advisory committee would be created to provide future oversight. The membership of the advisory committee would mirror that of the task force. Its functions would include establishing training requirements, providing credentialing and classifying new devices and procedures.

Collaboration Challenges

As the Medical Spa Task Force reviewed information from various perspectives, it had to confront and overcome obstacles. One such challenge was related to how the various professional boards monitor licensed facilities and who would be responsible for monitoring the entities covered under new regulations. The Boards of Medicine and Nursing traditionally rely on the Department of Public Health to assess health and safety issues in licensed facilities. The Board of Cosmetology regulates both the licensee and the work site. Since a medical spa would be a licensed facility employing professionals with a variety of credentials, this conflict needed to be resolved. The task force determined that the best approach would be to establish a new licensing board for advanced estheticians. This board would function independently of the Board of Cosmetology and its licensees would have to meet expanded education and training requirements in line with task force recommendations. The Massachusetts Legislature will need to approve the creation of the new licensing board, a process which can take up to two years.

Massachusetts is well on its way toward implementing clearer regulation of medical spas. Participants hope the Medical Spa Task Force findings will be introduced in a bill to the state legislature in 2009. Whatever the outcome, this innovative and coordinated approach of regulating a single entity with input from a consortium of state agencies and professional boards may pave the way for other states struggling to regulate the use of new medical aesthetic technologies.

Andrea Nadai, senior consultant, Boston MedTech Advisors (bmtadvisors.com) directs the Laser and Intense Light Information Service (LILIS), which provides information on state regulations and professional board recommendations to manufacturers, distributors and LIL service providers. Contact her at anadai@bmtadvisors.com.