





MASSACHUSETTS LEGISLATIVE INITIATIVE COULD RADICALLY CHANGE MEDICAL SPA INDUSTRY



By Alison Sahoo, Contributing Editor

After extensive research into their local medical spa segment, a Massachusetts task force has drafted a bill recommending training and supervision requirements for certain procedures. If passed this bill would also establish medical spa licensing and ownership rules to both new and existing practices in Massachusetts. This controversial proposal will soon be filed in the state's House of Representatives and Senate. Not only would the bill impose significant requirements and regulations upon medical spas within Massachusetts, it could serve as a model for similar legislation in other states.

Massachusetts Legislative Initiative Could Radically Change Medical Spa Industry

According to Russell Aims, chief of staff of the Massachusetts Board of Registration of Medicine (Boston, Mass.), "There wasn't a single precipitating event for the proposal. It resulted from the growing realization that the industry was expanding rapidly and therefore it was necessary to ensure public safety without putting excessive burden on private enterprise."

Along with state senator Joan M. Menard and representative Peter Koutoujian, the broad based discussion group included dermatologists, plastic surgeons, nurses, electrologists, cosmetologists, members of the public and officials from the department of public health (DPH), the division of professional licensure and the board of registration in medicine.

Unlike groups in other states, Mr. Aims believes that the Massachusetts task force was entirely focused on public safety. "Despite what you might expect, there was not a territorial mentality between the professions," he shared. "The task force spent two years developing what we feel is a coherent and comprehensive set of recommendations to regulate medical spas."

"I like that the proposal focuses on training and qualifications," said strategic consultant Peter D'Errico (South Walpole, Mass.). "Poor training is usually at the heart of adverse effects when they occur. While the proper emphasis is given to dermatologists and plastic surgeons, this proposal does allow for others to own and provide laser treatments with the proper training and license. This includes delegating qualified physicians and registered nurses as clinical directors."

Aesthetic businesses are segmented into three classes based on risk to the patient. Level I procedures are strictly cosmetic, such as hair and nail care. Level III procedures fall under the definition of practicing medicine or nursing and must be performed by a licensed physician or a registered

nurse (R.N.) in collaboration with a physician. Treatments between these two spectrums, such as laser hair removal, are deemed Level II. Since Level II and III procedures pose the greatest risk to patients, the proposed training and supervision requirements focus on these groups.

"As long as it's not onerous, any new regulation that improves the quality of results and enhances patient safety is a step in the right direction," added Mark Tager, M.D., an aesthetic industry consultant in San Diego, Calif.

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According to Jeff Russell, executive director of the *International Association for Physicians in Aesthetic Medicine* (IAPAM) located in Las Vegas, Nev., "Every state needs stronger training requirements. We're seeing medical malpractice companies mandating certifications from family practitioners, OB/GYNs, internists and other non-core physicians." More comprehensive training could also help medical spas in the course of their own business. "Insurance companies are the biggest advocates of additional training and often make it a requirement for medical spas to obtain insurance at all," he noted.

In its final report, the Massachusetts task force recommended that medical spas be licensed by the DPH in a manner similar to the way in which it licenses medical clinics. Similar to clinic and nursing home licenses, medical spa licenses would need to be renewed every two years. The legislation also sets forth requirements and restrictions for medical spa ownership, staffing and inspection.

A facility that performs Level II or III services would be exempt from medical spa licensure if it is solely owned and controlled by an actively practicing physician, nurse or electrologist with the appropriate training to provide these services. However, if a practice has multiple locations, the additional sites must each obtain a medical spa license unless the owner actively practices at each location.



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Level I Proposed Massachusetts Education and Training Standard

<p>TYPICAL PROCEDURES</p>	<ul style="list-style-type: none"> • Electric modalities • Ultrasonics • Heat treatments • Mechanical modalities (e.g. superficial microdermabrasion; superficial exfoliation; superficial lymphatic drainage from the bust line up; massage limited to lower extremities; and full body wraps) • Chemical modalities (e.g. hair perming or coloring) • Light-emitting diodes 	<ul style="list-style-type: none"> • Application of cosmetic preparations • Depilation • Beautification treatment (e.g. make-up artistry) • Nail care (e.g. manicures, pedicures, artificial nails) • Chemical peels (glycolics equal to, or less than 30% or buffered only) • Hair dressing • Scalp care • Non-invasive cellulite treatment
<p>LICENSE REQUIREMENTS</p>	<p>Cosmetologist and Basic Aesthetician, Advanced Aesthetician, Electrologist</p> <p>Level I procedures in scope of practice of advanced aestheticians only:</p> <ul style="list-style-type: none"> • Non-invasive cellulite treatment • Superficial dermaplane exfoliation • Ultrasonics (therapeutic, not diagnostic or surgical) 	<p>Level I procedures in scope of practice of electrologists:</p> <ul style="list-style-type: none"> • Electric modalities (thermolysis and blend for hair removal only)
<p>SUPERVISION REQUIREMENTS</p>	<p>None required</p>	
<p>RECOMMENDED TRAINING BEYOND LICENSE</p>	<p>None required for cosmetologist, basic and advanced aesthetician or electrologist. The cosmetology board's and electrology board's position is that their licensees may perform Level I services in a medical spa or any other facility, unless the specific procedure has been designated a Level II treatment when performed by either an R.N. or M.D.</p> <p>The boards of cosmetology and electrology disagree with the following: Those nurses or physicians without a cosmetology or electrologist license wishing to perform any of the Level I procedures will be required to show evidence that demonstrates competence in performing these functions and may only do so in a Level II or Level III environment.</p> <p>Competency includes successful completion of a training course with a comprehensive didactic component and a supervised practicum where each of the procedures is evaluated by a qualified practitioner who is also duly licensed as a cosmetologist, electrologist, nurse or physician, and in possession of the necessary credentials to provide education. A training course must include:</p> <ul style="list-style-type: none"> • Knowledge and understanding of anatomy, physiology and dermatological conditions where these modalities may be applied. • Knowledge and understanding of how to manage simple and anticipated side effects such as swelling, minor burning or infections that do not require medical intervention and when to refer to a medical provider. • Knowledge and understanding of any and all products/equipment used to deliver these modalities. 	

Source: Massachusetts Board of Registration in Medicine

In Level II and Level III medical spas, clinical/medical directors must be physically present for at least 10% of the office hours each month and available for consults and referrals. They must also have site directors present during all hours of operation that are trained and credentialed to oversee all licensed professionals.

If a business is exempt from licensure, it cannot use the term medical spa or anything similar to describe its business to the public. Instead, it must refer to itself as an office practice providing aesthetic services or simply as the office of its owner. Other details for medical spa licensure and operations would be defined by regulations promulgated by the DPH when and if the proposal passes.

Creation of a Board of Registration of Aestheticians was also recommended by the task force. In Massachusetts, aestheticians are currently licensed by the Board of Registration in Cosmetology, but research revealed that the degree of skincare practiced by aestheticians was quite different from the routine hair and nail care performed by cosmetologists. The task force recommended the establishment of an advanced license that would allow an aesthetician to perform a range of Level II procedures such as laser and light-based therapy, hair removal and other treatments not included under the current aesthetic license.

Under the new proposal, patients would have to be assessed by a physician, a physician's assistant, an R.N. or an advanced practice R.N. before any light-based skin procedure. This would address various medical concerns, such as the possibility that seemingly benign precancerous blemishes would go unnoticed and therefore untreated.

With new products, devices, technologies and procedures continually being developed, the task force also proposed the creation of a standing advisory committee to periodically review new treatments to determine their classification and the level of training and supervision required for those performing them.

Another recommendation included no longer classifying laser hair removal as the practice of medicine and eliminating a ban on the sale of goods from physicians' offices. This would allow physicians' in Massachusetts to retail cosmeceuticals, home-use aesthetic devices and other products, as physicians in most other states already do.

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Not everyone is happy with the proposal. "This is the wrong thing for the wrong reason," cautioned Eric Light, president worldwide of the *International Medispa Association* and CEO of the Strawberry Hill Group (Mainville, Ohio). Mr. Light believes that when the bill is submitted, it will strongly favor dermatologists. "The *American Society of Dermatologic Surgery* (ASDS) has been the driving force behind this legislation, and their goal is to keep this business within their profession." The problem with that is that dermatologists aren't necessarily experts in aesthetics since most have never had specific training in aesthetic treatments. When it comes to patient safety, family physicians, emergency room physicians and others may have the edge," explained Mr. Light.

"A family physician may approach aesthetics holistically and know more about a patient's underlying condition," advised Mr. Light. "Emergency room physicians work with a wider variety of technologies than dermatologists and see more burns. Ophthalmologists know the most about the structure surrounding the eye, so why shouldn't they be allowed to perform eye area injections? It should be about the quality of training."

"Furthermore, dermatologists are often booked weeks in advance and depending on the grandfather provisions in the bill, businesses that don't meet the new requirements may be forced to close," Mr. Light continued. "This could result in reduced competition, less competitor pricing analysis and layoffs – an unattractive outcome in a weak economy."

"If it's overly restrictive, it could make it too expensive to operate a medical spa," added Mr. Russell. "A physician doesn't want to spend an hour performing intense pulsed light (IPL) treatment on a man's back. It's not a technique dependent skill and an R.N. is perfectly capable of handling it. A physician's time is a lot more expensive than a nurse's time."

Level II Proposed Massachusetts Education and Training Standard

TYPICAL PROCEDURES	<ul style="list-style-type: none"> • Non-ablative, non-vaporizing laser and light devices (for hair removal and skin Tx) • Light-emitting diodes • Intense pulsed light (IPL) therapy (for hair removal and skin Tx) • Radiofrequency devices (mono/bi-polar and combination modalities (for skin tightening and photorejuvenation, etc.)) • Ultrasonics (diagnostic or surgical) • Exfoliation (superficial and non-superficial) • Microdermabrasion (superficial and non-superficial) • Dermaplane exfoliation (superficial and non-superficial) • Lymphatic drainage – whole body (superficial and non-superficial) • Chemical peels (glycolics equal to or less than 30%, or unbuffered)
LICENSURE REQUIREMENTS	<p>For an electrologist:</p> <ul style="list-style-type: none"> • Non-ablative laser device for hair removal only <p>For an advanced aesthetician (not cosmetologist or basic aesthetician):</p> <ul style="list-style-type: none"> • Non-ablative, non-vaporizing laser and light devices for hair removal only • IPL for hair removal only • Radiofrequency devices • Lymphatic drainage – whole body <ul style="list-style-type: none"> • Nurses and Physician Assistants, pursuant to supervisory guidelines • Advanced Practice R.N.s (APRN) • M.D.s <p>Level I procedures that become Level II procedures when performed by R.N.s and M.D.s including:</p> <ul style="list-style-type: none"> • Light-emitting diodes • Superficial exfoliation • Superficial microdermabrasion • Dermaplane exfoliation (superficial)
SUPERVISION REQUIREMENTS	<p>None required</p>
RECOMMENDED TRAINING BEYOND LICENSURE	<ol style="list-style-type: none"> 1. Certification from the <i>American Society for Laser Medicine and Surgery (ASLMS)</i> when available and when determined to provide sufficient evidence to the appropriate boards of registration that the content measures the necessary prerequisite competency for Level II practice or specialty certification from the boards of dermatology or plastic surgery where a residency, fellowship or other suitable clinical experience in the modality was achieved within the past seven years or the successful completion of a Cosmetic Laser Fellowship. <p>or</p> <ol style="list-style-type: none"> 2. Evidence that demonstrates compliance with Level II basic performance competency criteria earned through an approved CME or electrology/aesthetic/nursing CEU program of eight hours focusing on: <ul style="list-style-type: none"> • Knowledge and understanding of anatomy, physiology, pathology and how the modality is used. • Wound healing and repair. • Basic physics and safety issues relating to use of the modality. • OSHA and ANSI standards applicable to the device/modality. • Patient selection and assessment and when to refer a patient to a medical provider for consultation. • Device/modality management including indications, contraindications and evaluation of outcomes. <ul style="list-style-type: none"> • Knowledge and understanding of how to manage side effects such as swelling, erythema, minor burning or simple infections/inflammations, and when to refer to a medical provider. • Successful completion of a faculty supervised/precepted practicum of eight hours on each device/modality where the demonstration of competency can be assessed by qualified faculty using standardized outcome measures and who will attest to the competency of the trainee. <p>For microdermabrasion, chemical peels, lymphatic drainage, exfoliation, cryotherapy and electrocautery:</p> <p>Evidence that sufficiently demonstrates compliance with Level II basic performance competency criteria earned through an approved CME or electrology/aesthetic/nursing CEU program of eight hours focusing on:</p> <ul style="list-style-type: none"> • Knowledge and understanding of anatomy, physiology and dermatological conditions and how the modality is used. • Knowledge and understanding of how to manage side effects such as swelling, erythema, minor burning or simple infections/inflammations, and when to refer to a medical provider. • Knowledge and understanding of any and all products/equipment used to deliver these modalities.

Source: Massachusetts Board of Registration in Medicine

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While prices vary, the cost for laser and IPL instruction consisting of both didactic and hands-on training can run as high as \$10,000. Basic courses are priced between \$3,000 and \$5,000 but typically do not exceed basic laser hair removal and only offer limited practical experience.

It's unclear right now how restrictive the Massachusetts bill will be in limiting medical spa oversight to certain specialties. It's also uncertain if the bill will prevent non-physicians from performing selected procedures.

While many states have no medical spa regulations, others are quite restrictive, and some states are currently

“While many states have no medical spa regulations, others are quite restrictive, and some states are currently enacting new laws.”

enacting new laws. Drew Carlson, director of public affairs for the Federation of State Medical Boards (FSMB), noted that the lack of national guidelines for the regulation of medical spas keeps interest in this area high and the FSMB continues to offer information programs on the topic to its members.

Level III Proposed Massachusetts Education and Training Standard

TYPICAL PROCEDURES	<ul style="list-style-type: none"> • Ablative laser and light source devices • Injectables • Tissue alteration
LICENSURE REQUIREMENTS	<p>R.N. APRN Physician Assistant M.D.</p>
SUPERVISION REQUIREMENTS	<p>R.N.: Injectables and tissue alteration only pursuant to a prescription issued by a duly authorized prescriber and who is available for medical supervision by telecommunication methods for consultation and/or referral, and who can assess a client within four hours of treatment when requested by the nurse or patient</p>
RECOMMENDED TRAINING BEYOND LICENSURE	<p>For all clinicians performing Level III procedures: Evidence of attention at and completion of a course of at least eight hours in length for injectables and at least eight hours in length for tissue alterations. Each course must include:</p> <ul style="list-style-type: none"> • Knowledge and understanding of anatomy, physiology and cosmetological indications; where and when these modalities may be administered. • Knowledge and understanding of how to manage side effects such as swelling, erythema, minor burning or simple infections/inflammations and when to refer to a medical provider. • Knowledge and understanding of any and all products/equipment used to deliver these modalities. • Successful completion of at least ten of each procedure under a qualified faculty supervised practicum and evaluated by the qualified practitioner who is also duly licensed as a nurse or physician and in possession of the credentials to provide education.

Source: Massachusetts Board of Registration in Medicine

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Arizona's medical spa laws are among the toughest in the country. With the exception of physicians, all laser and IPL operators must undergo a comprehensive, state approved training program that includes both didactic and hands-on education. However, there are no other training or credentialing requirements, so anyone in Arizona can perform the treatments as long as they've successfully completed the training program.

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In California, laser treatments and injections must be performed under physician supervision. The ASDS lobbied for another law last year (CA Assembly Bill 2398) that would have required physician ownership of medical spas and shut down all existing medical spa businesses not owned by physicians. However, the proposal didn't pass.

In Florida, a law took effect in July 2006 saying that only board certified or board eligible dermatologists and plastic surgeons can supervise a medical spa unless the facility is located in the physician's own office. Therefore a family physician could not be a medical spa director but he could offer aesthetic treatments in his own practice.

The North Carolina Medical Board approved a statement in mid 2005 saying that each laser hair removal patient must first be examined by a physician, a physician assistant or a nurse practitioner. As well, a physician is expected to provide adequate oversight before and after the procedure. This statement was issued after a college student applied an anesthetic gel to her legs in preparation for laser hair removal and died several days later.

The Mississippi State Board of Medical Licensure asserts that, “any laser therapy performed in the state should be the responsibility of a licensed physician. Whether this is under the direct and close supervision of a physician or the physician is readily available to the person they have designated to perform the treatment is

the prerogative of that physician; however, he is responsible for the person he is supervising.”

Washington State deems treatment with laser, light, radiofrequency and plasma devices as the practice of medicine and stipulates that regardless of who performs treatment, the physician is ultimately responsible.

Alabama's laws are similar to those of California. In New Jersey, only physicians can operate lasers and IPL devices. Nevada hasn't passed any new laws yet, but a task force has been studying the issue for more than a year.

As of early 2009 it was still too soon to predict the fate of the Massachusetts proposal. Mr. Russell noted that medical spa laws in some states have passed quickly while others have stalled and died. “At first it seemed that the California legislation would be passed, but in the end it wasn't which was a surprise.”

On the other hand, the Massachusetts legislature runs on a two year cycle, therefore bills submitted in the first year of that cycle automatically carry over into the second year without re-filing. Consequently, once the new medical spa proposal is officially filed, referred to a committee, then vetted during a hearing, it has plenty of time to gather support before the actual vote. ■