

Massachusetts
Board of Registration in Medicine

Medical Spa Task Force



Presentation to the
Massachusetts Academy of Dermatology

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Why a Task Force?

- Growing understanding of spa phenomenon
- Anecdotal stories, e.g., walk-in Botox™ injections
- Multiple regulatory boards & stakeholders involved
- Clear lack of coherent, comprehensive regulatory structure
- Need for legislative involvement & support

Certainly the various boards of registration could have put together a task force on their own, but having a bill passed gave the group more weight, and brought on board vital legislative support for the eventual recommendations.



What are other states doing?

- Wide variety of regulation – from nothing to quite restrictive
- Mostly opinions expressed by Medical Boards, not specific comprehensive regulation
- California: only physicians can do injections; laser only under physician supervision
- Alabama: Similar to CA
- Nevada: Essentially no regulation

Just some examples. Few, if any states have comprehensive regulatory schemes addressing all potential medical spa procedures. Where regulation has been put in place, it usually involves laser only, sometimes there are state board opinions issued about injection. But – few if any have addressed pulsed light, dermabrasion, sclerotherapy or the whole host of other spa procedures that are going on in the marketplace.

And I don't believe anyone has really addressed ownership issues in the context of non-physicians, or of multiple sites, and how supervision is to be exercised in those situations. In general, most of the responses I got from other states was, "We so glad you're looking into this. Let us know what you come up with, because we're nowhere."



Assumptions

- Patient Safety is the goal
- This is a new model of regulation for a new type of medical setting
- We will need to live with scope overlap

As always, patient safety, patient safety, patient safety.

Medical Spas combine services previously performed in separate settings, and so a new type of regulation is needed to take that into account. How do you regulate a space where hair care and Botox injections are happening?

Because of this, there's going to be some overlap between agencies originally set up to police a single profession. Will each agency with professionals in a spa have to inspect the facilities? Can that be delegated to a single agency, like the Dept. of Public Health?



Principles

- Professionally acceptable
- Publicly credible
- Administratively feasible
- Economically affordable
- Legally defensible
- Individual Boards of Registration retain authority of their licensees and their scope of practice

Pretty straightforward:

The professions have to buy into the regulatory scheme

The public has to believe it will work and won't restrict their choices needlessly.

State government has to come up with a way to regulate that work.

Regulation cannot add substantially to the cost of medical spas

Because this is a new model of regulation, the legal underpinnings have to be thought through carefully.

Each Board knows its own licensees best, and should continue to regulate their practice.



Approach

- What (The procedures)
- Who (Who can perform them)
- Where (How will the facilities be licensed, staffed and operated)



Approach

- Classify Medical Spa procedures into Levels of ascending risk
- Practitioners may perform procedures only in Level(s) consistent with their scope of practice
- Appropriate supervision required for each Level

From the classification of procedures by Levels, everything else follows – who can do them, and how the facilities where they are performed need to be regulated.



Level I: Traditional Salons

- Who:** Cosmetologists/Aestheticians
- Where:** Salons regulated by the Board of Cosmetology
- What:** Electricity
Non-therapeutic Ultrasonics
Saunas
Mechanical
Chemical

Pretty simple: Level I only facilities are your basic beauty salon. It's only when Levels II and/or III are also performed that it becomes a medical spa. For these Level I facilities, nothing would change from the current regulatory set-up – it will remain with the Board of Cosmetology



Level I (continued)

LED

Application of cosmetic preps

Depilation

Beautification

Nail Care

Hair Care

Scalp Care

As you can see, just the standard beauty salon things.



Level 1 (continued)

Superficial Microdermabrasion

Low Level Chemical Peels

Lymphatic Drainage (above bust line)

» A Level I salon shall not include the word "medical" or any derivative thereof in its title, nor shall it advertise itself as offering or performing medical or nursing services



Level II: Medical Spa

Who: Nurses
Physicians
Electrologists & others –*to the extent of their Board-authorized scope (Example: Electrologists and Laser Hair Removal)*

Where: Medical Spas licensed by the Department of Public Health (certain exceptions apply)

There is still some conversation about who can do certain procedures. We're pretty clear on electrologists and laser hair removal, but discussion continues on, for example, whether estheticians can do laser skin procedures. The concern, of course, is someone not recognizing the difference between a pre-cancerous lesion and a normal brown spot.



Level II: Medical Spa

Where (continued)

Exceptions:

1. Carve-out for private offices
2. Within a medical spa there will be a requirement for joint regulation with the Boards of Cosmetology & Electrology if and when the spa employs or contracts with one or more of their licensees
3. If an individual holds both nurse and cosmetology licenses then the space shall be regulated solely by DPH even if Level I procedures are performed by the nurse

We continue with the existing regulatory carve out for private offices. DPH licenses clinics, but not individual physician offices, for example. This is a Massachusetts thing that may not be the case in every other state, but is of longstanding here.



Level II: Medical Spa (continued)

What: Microdermabrasion
Chemical Peels
Lymphatic Drainage (full body)
Non-Ablative and Non-Vaporizing
Laser Devices
IPL
Combination Modalities – *of
those therapies already in the level*
Tissue Alteration

Remember the general principle here is procedures are assigned to the Levels based on potential risk to the patient.



Level III: Medical Spa

Who:	Physicians Nurses- <i>to the extent of their Board authorized scope</i>
Where:	Medical Spas licensed by the Department of Public Health – except if performed in a private office " <i>carve-out</i> "
What:	Laser and Light Injectables Tissue Alteration Cryotherapy Electrocautery

Level III procedures are essentially the practice of medicine, and will be regulated in that fashion. Therefore, only physicians, and nurses properly authorized within their scope of practice, can perform these procedures. No one else. PAs could do some of these, but we don't talk about them too much, because a PA is completely tied to a physician's license and cannot act independently, and that would not change in the medical spa setting.



Medical Spa Licensure

Facility Concepts for Level II:

1. Licensure will be by DPH
2. Level II Medical Spas will be managed administratively by a Site Director and a Clinical Director (may be same person) the qualifications for which will be defined in DPH regs
3. Clinical Directors must be physically present for at least 10% of office hours per month and be available for consult and referral



Medical Spa Licensure

Facility Concepts Level II:

4. Clinical and Site Directors must be qualified to perform Level II procedures
5. Site Directors responsible for site-based credentialing of all licensed professionals on staff, adequate back-up coverage, training, continuing education, etc. Must be on-site during all hours of operation.



Medical Spa Licensure

Facility Concepts Level III:

1. Level III Medical Spas will have a Medical Director and Site Director appropriately trained to perform and supervise Level III procedures.
2. Medical Directors must be on-site at least 10% of office hours per month, and available for consult and referral.
3. Similar Site Director duties for credentialing, etc. Must be on-site at all times.
4. Standardized Medical Spa policies & procedures outlined in regulations including such things as staffing requirements, physical plant & records retention.



OWNERSHIP ISSUES

1. "Private Office Exemption": Entity solely owned by a physician, nurse or electrologist who has the required training and experience and is actively practicing during hours of operation can perform Level II & III procedures without DPH licensure.
2. Private Office cannot be called Medical Spa, only an office providing Level II & III services, or simply as the "Office of Dr./Nurse/Electrologist _____"

Ownership is a potential problem, because some of the issues we are trying to address/avoid are:

One person physician, for example, owns multiple medical spas, and serves as the medical director of all of them – doesn't that spread "supervision" pretty thinly?

You can't assert the private office exemption, and still call yourself a medical spa, because that term implies services, training and staffing beyond what would normally be found in a private office.



OWNERSHIP ISSUES

3. For an office practice with multiple sites, additional sites will require DPH licensure unless each additional site is staffed at all times by another owner.
4. That additional owner must also possess the required training and experience to supervise Level II & III procedures

A group of physicians, for example, COULD still have multiple office locations, but each location would have to be staffed full time by at least one of the group practice owners. And, of course, each person would still need appropriate training.



Sale of Goods

- AMA policy:
“In-office sale of health-related products by physicians presents a financial conflict of interest, risks placing undue pressure on the patient, and threatens to erode patient trust and undermine the primary obligation of physicians to serve the interests of the patient before their own.”

American Medical Association Code of Ethics
Section 8.063 “Sale of Health-Related Products from
Physicians’ Offices”, Adopted June 1999.



Sale of Goods

- Current MA Board Policy Excerpt:

“Physicians should not sell, lease or rent any product in a manner that has the potential to exploit patients, including but not limited to exclusive distributorships or personal branding.”

Sale of goods in a medical spa, however, is arguably an integral part of the business operation. And many of the products sold are necessary to enhance the treatment or make recovery easier. This is a good example of how this new type of practice environment spurs new thinking on established policies. And it's something the Task Force did not initially realize would be an issue to address.

One example is various gels/creams that one would apply after a facial dermabrasion.

The MA Board will likely adopt a revised sale of goods policy, based on North Carolina's to allow sale of goods related to medical aesthetic procedures in physician offices and medical spas. Products will not be displayed in any exam or consultation rooms or anywhere patients are treated, however.



Sale of Goods

- Probable revision to MA Board policy
- Sale of goods related to medical aesthetic procedures in Spa or private office allowed
- No display or sale in any exam or consult room, and no room patients are treated
- Guiding concept – what is in the best interest of the patient



Laser Hair Removal

- Current MA Board policy: It is the practice of medicine
- Probable new policy: It is not the practice of medicine
- Rationale: Electrolysis being replaced by laser; low risk, and adverse impact on electrologists unnecessary



Going Forward

- Medical Spa environment is ever-changing
- Cannot rest on static regulations or policies
- Need for advisory group to recommend changes periodically
- Proposed statute includes advisory group similar in composition to Med Spa Task Force to advise DPH Commissioner
- Example: what Level should a new type of procedure or technology be assigned?



BOARD OF REGISTRATION IN MEDICINE WEBSITE

[HTTP://WWW.MASSMEDBOARD.ORG](http://www.massmedboard.org)

I always put up the website, and they can find a bunch of stuff on med spa there.

QUESTIONS?

