

-DRAFT- MINUTES
MASSACHUSETTS BOARD OF REGISTRATION IN MEDICINE
MEDICAL SPA TASK FORCE

May 23, 2007

PRESENT

Task Force Members

Boards:

Gino Chisari, RN, Board of Registration in Nursing
Barbara Kellman, JD, Board of Registration in Nursing
Kathe Mullally, JD, Board of Cosmetology
Catherine Hinds, Board of Cosmetology

Legislature:

Senator Joan Menard

Appointees:

Stephanie Cogliano, RE
Jeffrey Dover, MD
Faye Marie Jenkins, RN
Karen McKoy, MD
Dianne Quibell, MD
Jagruti Patel, MD
Winifred Nee Tobin, Consumer

Absent:

Nancy Achin Audesse, Board of Registration in Medicine
Jennifer Infurna, Representative Koutoujian staff
Winifred Nee Tobin, Consumer

Board Staff

Russ Aims, Board of Registration in Medicine
Brenda Beaton, JD, Board of Registration in Medicine
Kathleen DiTonno, Board of Registration in Medicine

1. Welcome, Goals for Today's Discussion

Welcome- Russell Aims, Special Assistant to the Board of Registration in Medicine, called to order the meeting of the Medical Spa Task Force. Mr. Aims expressed his goal of today's Task force meeting which includes discussion about running through the list, as previously provided by Kathe Mullally, Esq., of medical spa and salon procedures. Level One procedures had been discussed prior to today's meeting and Mr. Aims wishes continued discussion to categorize Level Two and Level Three procedures. The next meeting of the Medical Spa Task Force will be on June 6, 2007. Senator Joan Menard states that she had a legislative reporting date of May 19th regarding the progress of the Task Force, the Task Force would then have ninety days from that point to extend the date for providing draft regulations to Legislature. In order to prevent the Task Force from being rushed, it was agreed that the Senator would extend the reporting requirement into September. There would be no issue if the Task Force completed work prior to September and the group would still be able to present to Legislature. The Task Force will review any draft going before the Legislature.

2. Discussion of Proposed Regulatory Framework

Mr. Russell Aims now led the group into discussion about the three levels of Medical Spa/Salon Procedures. It was discussed that while the task force will define a number of procedures and who may perform them, the Task Force does not wish to become preclusive in definition, so that there will remain some leeway for future advisory policies.

Mr. Aims asked the Task Force if everybody was in agreement of the list of Level One procedures at which time the question was raised if Level One had been defined. Simply, Level One would be the lowest risk procedures, rather than specifically what it is and who performs the procedure. The group then went into detailed discussion regarding who may perform procedures at each level. Level One procedures could be performed by persons appropriately licensed by the Board of Registration of Cosmetologists as well as those licensed by the Board of Registration in Medicine and the Board of Registration in Nursing. There was concern that registered physicians and nurses would be excluded from doing procedures that are currently used and permitted by their respective licensing boards. Also expressed were some concerns that conversely, physicians and nurses who are licensed respectively but not qualified would be permitted to perform Level One procedures. It was agreed that physicians and nurses would be permitted to perform Level One procedures without separate cosmetology and/or aesthetician licenses, however, it was stressed that these procedures would be done only if the individual had adequate experience and training, and the procedure was within the scope of standard therapeutic medical practice as opposed to being a beauty treatment. Mr. Chisari stated that it would be up to the individual Boards of Registration to determine if the procedure done is within one's scope of practice. The responsibility would remain with each licensee to ensure that one is appropriately trained to perform a procedure, and if not, the standard of being held accountable remains. The Boards of Registration do have the authority to

sanction, and licensees will continue to have an obligation to report persons practicing outside of their ability.

The following list of procedures was determined to fall within a low risk, and therefore Level One procedures: ELECTRICITY; Galvanic Current, Thermolysis, Blend, Iontophoresis, Cryoelectrophoresis, Electrotherapy, Cathiodermie. ULTRASONICS; Therapeutic (excludes use for diagnostic and/or surgical purposes). HEAT THERAPY; Saunas. MECHANICAL; Exfoliation (superficial), Microdermabrasion (superficial), Dermaplane Exfoliation (superficial), Lymphatic Drainage (superficial), Non-Invasive Cellulite Treatment (superficial), Massage (hand to elbow, foot to knee, face, full body wraps). CHEMICAL; exfoliation (superficial), Microdermabrasion (superficial), Chemical Peels (superficial), Hair coloring and perming. APPLICATION OF COSMETIC PREPARATIONS; Clean, manipulate and stimulate skin via facials, face masks and body wraps and paraffin wraps. DEPILATION; Tweezing, Waxing, Threading, Sugaring. BEAUTIFICATION; Make-up application and artistry, manicures, pedicures, nail care, artificial nails and polish, hair dressing, scalp care. TISSUE ALTERATION: Electrical

It is agreed that this is a comprehensive list as possible at this time. Ms. Mullally will compile an additional list to address combined modality Level One procedures (skin peels, dermal electric, titration, double peel) which can be memorialized at the next Task Force meeting.

The following list of procedures was determined to be medium risk, and therefore Level Two procedures: COMBINATION MODALITIES: Photo-Dynamic Facials using ALA, Chemical plus light. INJECTABLES: Neuromodulators (Botulinum exotoxins)* TISSUE ALTERATION: Mechanical (exfoliation, microdermabrasion, dermaplane exfoliation, lymphatic drainage-all medium and deep) Chemical (exfoliation, chemical peels-both medium and deep, Chemical peels are defined by percentages- 30% glycolic acid), Electrical, Cryotherapy, Electrocautery. RADIO-FREQUENCY DEVICES-mechanical energy. LASER AND LIGHT**: Laser (non-ablative and non-vaporizing), ILP, Combination Device, LED

**Laser and Light: Classes of lasers are an outdated system and should no longer apply. Instead, the Task Force divided laser and light into four specific categories and assigned each a level category based on its level of risk. Specific treatment targets were also removed from the list so that the risk level is defined by the device used rather than by the target treatment.

1. Laser: Classified by ablative (surgical), micro-ablative or vaporizing lasers (Level Three) and non-ablative and non-vaporizing (Level Two)
2. Intense Pulsed Light Therapy (ILP)-Level Two
3. Combination Device- Level Two (light plus thermal for hair removal, intense pulse light plus radio frequency)
4. Light-Emitting Diode (LED)-Level One

Mr. Aims guided the group to continue reviewing the remaining list of procedures. Surgical procedures are the highest risk procedures and determined to be the practice of medicine. Some of these procedures may be done in a Medical Spa but are still considered to be the practice of medicine.

*It was noted that neuromodulators (Botulinum exotoxins) are a lower risk injectable, and while should be administered by or under the supervision of a licensed physician, it will be considered a Level Two procedure. All injectables are prescriptive pharmaceuticals and require a physician's order, though may not require direct, on-site supervision by a physician.

The following procedures were removed from the list of Med Spa/Salon Procedures. Ear candling-it is not an FDA approved treatment. Teeth whitening-should be performed by those licensed by the Board of Registration in Dentistry. Credo blades-use is not permitted in Massachusetts. Mesotherapy is not currently FDA approved. Body or ear piercing-this is regulated by local Boards of Health. Acupuncture-it is currently regulated by the Board of Registration in Medicine and requires separate licensure. Tattooing-currently regulated by local Boards of Health, but may be something that the Task Force should address. It will not be addressed at this time so as to not exclude it from future regulatory action of the Task Force. Physicians can currently tattoo for medical purposes, i.e. micropigmentation (permanent make-up). Eyelash tinting, dyeing, perming is not FDA approved or allowed by Massachusetts law. Invasive cellulite treatment-not FDA approved

Dr. Patel noted that it is not realistic to require that all physicians performing these procedures be board certified. Instead, Board Certified physicians, such as dermatologists, should be used as a resource, rather than the basic standard, so as to not exempt an appropriately trained non-physician from performing a procedure. As for all levels of procedures, every person performing any previously mentioned procedure should be held to the same standards. Each person's relative Board of Registration, (physicians, nurses, cosmetologists) would provide a level of standard and ethics for persons to determine if one is qualified to perform a procedure. Likewise, individual Boards of Registration will hold licensees accountable to work within the scope of their regulations via advisory rulings, which can be amended regularly. There was some discussion of whether or not it would be appropriate or possible for the Medical Spa Task Force to become a credentialing entity for persons working under the Med Spa regulations. Because of the minimal size of the task force, and the time, expense, and difficulties of becoming an accredited credentialing entity, this would not be possible. This will also make it difficult to determine what the minimum level of training one should have to be deemed appropriately trained. However, it would be a responsibility of the clinical director of a Medical Spa Facility, as licensed by the Department of Public Health (DPH), to ensure that persons working in a medical spa have met appropriate credential measures. If one is licensed (i.e. physician), but not qualified to perform a procedure (i.e. Level One non-medical procedures) they would be encouraged to hire a trained professional (i.e. cosmetologist). Again, if one works outside of the scope of his/her training and experience, he/she may be disciplined by his/her

individual Board of Registration. The Board of Registration in Medicine has placed a great deal of trust in the medical field. Because physicians will not need additional licensing to perform Level One and Two procedures, it will essentially be an honor system that physicians will perform a procedure because it is within the standard of therapeutic medical practice and remains within the scope of their training. The standard of being held accountable remains and the Board of Registration in Medicine does have authority to sanction inappropriate actions. Dr. Dover offered to provide the group with a comprehensive set of standards created and used by him, which has been provided to a number of facilities to help set a standard in determining the appropriate level of training for the use of lasers and similar equipment. This also includes some credentialing recommendations. Dr. Dover encourages the use of these standards within the Medical Spa regulations in order to facilitate the goals of the Task Force. Mr. Aims will distribute this to the group for review once available.

3. Approval of Minutes

Mr. Russell Aims brought forth a motion to approve the meeting minutes of the April 25, 2007 Medical Spa Task Force meeting.

A minor change was made in the last sentence of page 4 so that it read "... but they do credential physicians..." by removing the words "will not"

Dr. Quibell requested the additional note that she read a letter during the April 25th meeting regarding the limitation of advanced training in aesthetic training.

The meeting minutes were approved.

4. Next Steps

The next meeting of the Medical Spa Task Force is scheduled for Wednesday, June 6, 2007 from 8:00-11:00 am.