



STATE OF TENNESSEE
DEPARTMENT OF HEALTH
Bureau of Health Licensure and Regulation
Division of Health Related Boards
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COMMISSIONER

BOARD OF MEDICAL EXAMINERS

March 20, 2013

Tennessee General Assembly
1 Legislative Plaza
Nashville, TN 37243

Re: Summary of the Workgroup on Medical Spas

Dear Members:

The Board of Medical Examiners, upon the urging of the Tennessee Senate Health and Welfare Committee (pursuant to Senate Resolution 94), organized a workgroup of representatives from the following boards or committee to discuss and come to some agreements related to the delivery of cosmetic procedures and treatments in Tennessee.

Board of Medical Examiners (Chair)	Michael Zanolli MD
Board of Nursing	Don Bell APN PhD
Board of Osteopathic Examination	Karen Shepherd DO
Committee on Physician Assistants	Joan Gardner PA-C
Board of Cosmetology	Rachel Powers JD

(Replacing Dr. Bell at the February 21st meeting was Brent Earwood APN CRNA)

Meetings took place according to the Open Meetings Act, TCA 8-44-101-111, and at each of the three meetings sufficient time was allocated for public comment from those interested members of the public who expressed an interest in addressing the Workgroup. The three meetings took place at the Offices of the Health Related Boards on the following dates and times:

October 4 th , 2012	4-6 PM
November 15 th , 2012	4-6 PM
February 21 st , 2013	4-6 PM

There are three points agreed upon at the time of the first meeting of the Workgroup. This helped focus the discussion and allowed the members of the Workgroup to discuss the activities and delivery of treatments used for cosmetic or aesthetic purposes.

- Safety of the people who utilize available facilities for aesthetic treatments or enhancement of their appearance was our primary concern.
- Our discussions concerned the techniques, treatments, and medical aspects of the evaluation and treatment of those people who use such facilities. Our discussion did not include the civil or business aspects of such facilities.

The members of the Workgroup did not have any intention of making recommendations limiting or prohibiting the licensed activities and procedures for those professionals who are licensed and recognized by the Tennessee Cosmetology Board.

Summary of discussions

The Workgroup collaborated to define the problem related to delivery of aesthetic procedures in need of regulation to provide adequate public safety. The “gap” seems to be between the services provided by a licensed aesthetician or cosmetologist working within the scope of their licensure and a medical office.

Definition of a Medical Spa:

A Medical Spa is a facility specializing in various techniques and procedures intended for enhancement of the appearance of an individual. A Medical Spa would be staffed by medical¹ personnel licensed by the state of Tennessee for evaluation and delivery of a procedure or treatment by those persons performing such treatments.

Practice of medicine and how it relates to Medical Spas:

Sources of definitions and description of aesthetics/medicine/surgery contained in statutes and rules of the State of Tennessee used as the basis for the discussions include:

Cosmetology – TCA 62-4-102(b)

Medicine – TCA 63-6-204(a)(1)

Surgery – rule 0880-2-.21(3)(0)

The Work Group’s discussion was focused upon the various procedures or treatments provided by medical spas. There was recognition of the great variety and scope of services (procedures and treatments) used to affect the skin or skin structures or to enhance a person’s appearance by injection of biologically active materials or dermal fillers to modify the appearance of an individual. It was also recognized there is a graduated potential for the production of side effects with utilization of more inherently invasive or potentially dangerous procedures. These include injections of drugs and foreign materials, or use of electromagnetic energy (including lasers), as treatments. There was general agreement of the scope of various treatments associated with a range of potential significant and permanent side effects.

¹ Use of the term, “medical”, was favored by the BME, BOE, BON, and COPA. The Cosmetology Board representative was fearful the cosmetologists and aestheticians would not be included if characterized as medical. In this context and setting, the BME thinks the designation would include aestheticians and cosmetologists.

Guidance and clarity was afforded to the Workgroup through discussion of the Tennessee Attorney General's opinion, No. 12-91 (see attached). This opinion was evaluated and commented on by the representative of the Office of General Counsel, present at each of the three meetings. The AG's opinion clearly states that aesthetic services performed which exceed those procedures authorized under The Cosmetic Act would have to be performed in a medical office by a person licensed for that medical practice and within their capacity as a medical professional. The combination of the cited definitions regarding cosmetology/medicine/surgery taken together with the AG's opinion produced a general consensus from the Workgroup and the OGC that the procedures and treatments available at a medical spa are either defined under the practice of cosmetology or considered the practice of medicine. Once again, there was discussion of the range of the procedures and treatments available at a medical spa in addition to the variable potential for side effects.

Training

The acknowledgement of the skills and training of medical personnel performing the treatments would take into consideration the education and training required to qualify for and then be granted a license by the State of Tennessee in cosmetology, nursing, or medicine. In addition, there would have to be demonstrated medical education and proficiency in the use of the devices and procedures for all personnel including the supervising physician and/or medical director. Medical assistants or nurses aides can receive training for medical activities and obtain a certificate from the Tennessee Department of Health as discussed in the AG's opinion 12-91. There is further characterization from the opinion that, "Also, the nurse, assistant, or aide would not be exempt from the Act (Cosmetology Act) if he or she were to perform an activity that falls within both practices but the performance of the activity was not in his or her 'professional capacity' as a medical professional."

The Workgroup discussed the concept of professional capacity further. There was recognition that the medical professionals, even with advanced degrees such as APN, MD, or DO, performing or supervising procedures or treatments at a facility should also have to work within their professional capacity. More specifically, graduate medical education in an approved training program providing didactic and practical experience in the areas of medical and surgical treatments applicable to aesthetic or cosmetic procedures would be the basis for claiming professional capacity of a supervising physician and/or medical director. Similarly, non physician medical professionals would have to demonstrate formal training or completion of recognized training courses which would more fully define their professional capacity regarding specialized procedures and treatments not part of the curriculum of their professional school.

Supervision

Supervision of medical professional personnel at a medical spa would have to be either with direct or indirect oversight. There was clear and uniform agreement that direct supervision meant, "on the premises". Indirect supervision was subdivided to include immediate availability for contact during the times treatments were being delivered, and after hours contact through routine answering services or electronic means.

Responsibility

The responsible parties for the treatments delivered to patients would be the medical personnel who deliver the treatment and the supervising physician or medical director of the medical spa. Protocols would be required for aesthetic procedures or treatments beyond the scope of the cosmetology act as previously mentioned in reference to the AG's opinion 12-91. The responsibility for the proper evaluation of the patient, selection of the treatment, and use of the equipment would ultimately be the responsibility of the physician or medical director overseeing the medical personnel.

New and Advancing Technology

The development and adoption of new technology or variations of established techniques are continually occurring in the field of aesthetics. New medications, treatments, and new laser devices are appearing on the market and being promoted by the industry directly to medical spas and physician offices. Proficient and safe use of new equipment will require additional and ongoing training. Demonstration of the continuing medical education and proficiency of the use of new devices or techniques would be required of a medical spa facility with documentation of appropriate continuing medical education and training of personnel.

Closing

On behalf of the members of the Workgroup on Medical Spas, and as the representative of the Tennessee Board of Medical Examiners, it is our hope that the summary of the discussions of the Workgroup will help serve as the basis for consideration of the medical aspects related to the standards and principles for the safe performance of aesthetic and cosmetic procedures and treatments delivered at Medical Spa facilities in the state of Tennessee.

Respectfully submitted,

Michael Zanolli MD
President, Tennessee Board of Medical Examiners
Chair, Workgroup on Medical Spas