



*American Academy of Dermatology
and AAD Association*

Physicians Dedicated to Excellence in Dermatology™

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July 21, 2009

State Senator Susan Fargo, Chair
State Representative Jeffrey Sanchez, Chair
Joint Committee on Public Health
Massachusetts General Court
State House, Room 504
Boston, MA 02133

Dear Senator Fargo and Representative Sanchez,

On behalf of the more than 16,000 members of the American Academy of Dermatology Association (AADA or Academy), and the 389 dermatologists in Massachusetts, I am writing to share our concerns regarding SB 836. This bill would enact recommendations from the Massachusetts Medical Spa Task Force, and while we appreciate the dedication of the Task Force, we believe the limited representation of dermatologists on this decision making body led to flawed recommendations and unwarranted scope of practice expansions for physician extenders and non-medical personnel to perform cosmetic medical procedures. For the reasons set forth below, AADA opposes SB 836, as currently written.

SB 836 Endangers Patient Safety

As dermatologists, our utmost concerns are patient care and patient safety. Quality patient care includes evaluating a patient's needs and current condition, selecting an appropriate course of treatment, and providing adequate information and follow-up care. When non-physician practitioners are given legal approval to do the same procedures dermatologists spend years in medical and surgical training to perform, patient safety is seriously compromised. With the growing public demand and appreciation for cosmetic medical procedures, including intense pulsed light (IPL) and laser treatments, establishing scope of practice standards on who can perform these procedures is critically important.

The Academy believes the practice of cutaneous medicine includes, but is not limited to, performing any act or procedure that, by its intended or improper use, can alter or cause biologic change or damage living tissue. Such acts or procedures include, for example, the use of all lasers, light sources, microwave energy, electrical impulses, chemical application, particle sanding, the injection or insertion of foreign or natural substances, or soft tissue augmentation. Many of these types of procedures are included in SB 836 as level two procedures which can be performed by varied non-physician practitioners and other personnel without physician supervision in a medical

spa setting. AADA maintains that these procedures should be performed only by licensed physicians or under the direct, on-site supervision of a physician.

As noted, AADA is very concerned with the wide range of procedures classified as level two procedures by the Medical Spa Task Force and contained in this bill. Specifically, it is gravely important to have physician supervision of cosmetic medical procedures performed by physician extenders and non-medical personnel, such as aestheticians, electrologists and cosmetologists. Furthermore, the procedures being performed in a licensed medical spa should be within the scope of practice of those providing supervision. It is the opinion of the Academy that board-certified dermatologists and licensed physicians are the most appropriate, due to education and training, to provide supervision for level two procedures performed in a medical spa; yet, SB 836 defines these roles as being performed by “a physician or nurse licensed under the provisions of chapter 112.” As these directors fill the only supervisory role within a medical spa, the Academy feels strongly that both of these roles must be filled by a licensed physician. Therefore, in order to protect patient safety, AADA urges the Committee to amend this language in Section 221 by striking “or nurse” from these definitions.

To further protect the health and safety of patients, initial skin exams by a physician are critical. At current rates, one in five Americans will develop some form of skin cancer during the course of their lifetime. Melanoma, the deadliest form of skin cancer, kills one person every 62 minutes. With this explosion in incidence, it is imperative that a physician trained in cutaneous medicine evaluate each patient to ensure that they are an appropriate candidate for a cosmetic procedure, and that they do not have a preexisting skin condition, like skin cancer, that could be exacerbated or critically obscured through a laser or other cosmetic medical treatment. Laser, LED and IPL devices have the ability to alter the pathology of skin cancer, rendering it either undetectable or causing a late diagnosis. In the instance of melanoma, a misdiagnosis or delayed diagnosis could be fatal. It is absolutely crucial that prior to any cosmetic or dermatologic procedure, a patient receives an initial exam by a physician. AADA respectfully appeals to the Committee to amend Section 225 of SB 836 to read, “The clinical director or another experienced ~~nurse~~ or physician with appropriate training shall perform all [initial] patient assessments for level II procedures [prior to the procedure being performed] and shall make appropriate referrals to a collaborating physician as necessary.”

Cosmetic Medical Procedures Require Specific Education & Training

A recent study by Vic A. Narurkar, MD found that in examining 123 complications that were the result of a non-physician performing a laser procedure, the most common cause of complications was the use of a device for an improper indication and the next most common cause was overutilization of a device for an indication for which an alternative therapy was superior. These two problems accounted for 65 percent of the total complications (See Exhibit A attached). This data demonstrates the need to ensure adequate training and direct, onsite supervision for any cosmetic medical procedure. To this end, the definition of electrolysis in SB 836 should be amended.

SB 836 states, “Electrolysis, the method of removing hair from the human body by the application of an electrical or radiofrequency current to the hair-papilla by means of a needle or any other instrument or device to cause decomposition, coagulation or dehydration of the hair-papilla and thus permanently remove the hair. Said definition shall also include, but not limit other licensed professions from performing, the removal of hair from the human body by use of lasers or intense pulse light devices.” AADA urges the Committee to add the following language to end of this definition in Section 2, “...under the direct on-site supervision of a licensed physician in an exempt private office, or under the direct, on-site supervision of a clinical director or site director in a level II facility.”

Physicians performing cosmetic medical procedures have years of training in residencies to medically recognize and address complications. While complications can of course occur even in the best of hands, physicians’ additional training and expertise allows them to substantively reduce the incidence of complications and to recognize and treat them appropriately when they do occur. As more and more devices become available, as well as devices continuing to be approved for new indications, patient safety must remain the primary objective.

While AADA does not have educational standards for non-physicians performing laser procedures, the American Society for Laser Medicine and Surgery (ASLMS) does. We would recommend using their recommendations and principles as a guide for assessing the competency of a non-physician practitioner to perform laser procedures. ASLMS notes that only licensed medical professionals who have been trained appropriately in laser physics, tissue interaction, laser safety, clinical application, and pre and post operative care of the laser patient should operate a laser. Furthermore, their recommendations state that, “(a) minimum of 10 procedures of preceptor training should be required for each laser procedure and laser type to assess competency. Participation in all training programs, acquisition of new skills and number of hours spent in maintaining proficiency should be well documented.”¹ The Academy strongly supports the inclusion of educational standards and requirements for non-physician personnel to perform level two cosmetic medical procedures in a medical spa.

Ongoing Oversight and Decision Making Should Include More Physicians

SB 836 calls for the creation of a “medical spa advisory committee, composed of one representative each from the boards of registration in medicine, nursing, electrology and cosmetology appointed by each board’s executive director, one representative from the department appointed by the commissioner, one physician appointed by the board of registration in medicine, one nurse appointed by the board of registration in nursing, one electrologist appointed by the board of registration of electrologists, one licensed cosmetologist appointed by the board of registration in cosmetology, one advanced aesthetician appointed by the board of registration in cosmetology, one representative from a medical equipment manufacturer appointed by the department,

¹ Web, American Society for Laser Medicine and Surgery Educational Recommendations for Laser Use by Non-Physicians. www.aslms.org/public/standardserlnp.shtml

and one owner of a medical spa licensed by the department, and appointed by the department.”

AADA strongly supports the creation of this advisory committee with increased physician participation. As the procedures performed in medical spas can be classified as the practice of medicine, the advisory committee should be primarily governed by physicians whose scope of practice includes the ability to perform the majority of the procedures. The Academy believes this 12-member committee should be comprised of a minimum of six physicians, among other practitioners. While AADA understands the need to keep the size of the committee manageable for efficiency and effectiveness in its advisory role, we believe it is essential to ongoing regulation of the medical spa industry to incorporate additional physician input. We therefore respectfully ask the Joint Committee on Public Health to expand the size of the medical spa advisory committee or change its composition to include 50 percent representation by licensed physicians.

Penalties Must Deter Non-Compliance

Finally, Section 229 of SB 836 addresses penalties for the operation of an unlicensed medical spa. As written, the minimal penalties neither provide a significant barrier to compel a medical spa business to obtain a license as prescribed by the legislation, nor would it produce the necessary revenue for the state to undertake strict enforcement efforts. AADA strongly encourages the Committee to strengthen the monetary and legal penalties for illegally operating a medical spa. Increasing the monetary fines for a first offense to a minimum of \$2500, increasing the maximum length of imprisonment to four years and requiring the medical license of a medical spa owner, if applicable, to be revoked for a subsequent offense, will create an effective regulatory environment to guarantee compliance by medical spa operators.

For the reasons set forth above, and in order to protect the citizens of the Commonwealth of Massachusetts from adverse events resulting from cosmetic medical procedures, AADA opposes SB 836 as currently written. We appreciate the opportunity to provide written comments and amendment suggestions on this critical public health issue. For further information, please feel free to contact Kathryn Guccione, Assistant Director of State Policy for the American Academy of Dermatology Association, at (kguccione@aad.org) or (202) 712-2615.

Sincerely,



David M. Pariser, MD, FAAD
President, American Academy of Dermatology Association
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CC: Members, Joint Committee on Public Health