

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

Re: SB 836

Dear Senator Fargo and Representative Sanchez:

As President of the American Society for Dermatologic Surgery Association (ASDSA), a medical specialty organization representing over 5,000 physician members across the nation, I am writing to urge you to oppose SB 836, as it is currently written.

The issue of ensuring appropriate training, patient examination, physician oversight and supervision is particularly critical for non-ablative medical procedures, including laser and light-based hair removal, performed in non-traditional medical settings. **“Eighty two percent of all complications occurred in facilities that had no direct physician supervision. Of these, 57% were in facilities with a “medical director” who had limited training in dermatologic procedures and laser/light-based therapy. Of all the complications, 78% occurred in non-traditional medical facilities, such as free-standing medical spas and laser centers in shopping malls.”** (*Skin and Aging* (.Volume 13 - Issue 9_2005 - September 2005 - Pages: 70 – 71)

Allowing Electrologists to Perform Laser Hair Removal Puts Patients at Risk

Of particular concern is the definition of “electrologist” as one who could perform laser and light-based hair removal. At a minimum, electrologists should be able to perform these procedures only with on-site physician supervision and after an initial good-faith examination by a physician to ensure that the patient has no pre-existing conditions which would be exacerbated by the treatment.

Any procedure, including hair removal, which utilizes energy-based devices capable of altering or damaging living tissue performed on human beings for cutaneous conditions, should be considered as the practice of medicine. These lasers are classified as class IIIb or class IV by the American National Standards Institute (ANSI).

American National Standards Institute classified IIIb and IV lasers and intense pulsed light devices are considered by the FDA to be “medical prescription devices.” A “Prescription device,” is defined by the Code of Federal Regulations Section 801.109 as “a device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device...”

Additionally, **laser hair removal causes more complications than any other laser medical treatment**, according to a study published in *Skin and Aging* (.Volume 13 - Issue 9_2005 - September 2005 - Pages: 70 – 71) The study, “Analysis of Complications from Lasers and Light Sources and Radiofrequency Devices by Non-Physicians,” demonstrated that hair reduction was the most commonly treated condition that resulted in complications (46%), followed by laser/light leg vein treatments (21%) and non-facial photorejuvenation (11%). Lower extremities were the most common location of complications (36%), followed by face (22%) and neck (12%).

Consideration of laser and light-based hair removal as the practice of medicine is consistent with the American Medical Association and the American College of Surgeon’s definition of surgery, as well as other AMA laser surgery policy as cited in the attachment.

In fact, the American Electrology Association (AEA) cautions electrologists from using lasers for hair removal. According to the AEA Laser Position Statement, “The AEA has grave concerns regarding the standards of laser hair removal patient care. In this rapidly evolving and completely unregulated medical specialty, a technician, practicing in any field can use a laser on patients the very same day of purchase-directed only by the manufacturers’ representatives’ instructions. In some instances a ‘Rent a Medical Director’ is the ‘physician’ overseeing the clinic or tech.... Laser hair removal devices are now being sold for dual applications and vascular and pigmented lesions, sun damage and telangiectasias are the latest addition to this unregulated field. The health and safety of the unknowing public is at risk.”

Only 3 States Explicitly Allow Electrologists to Perform Laser Hair Removal

Despite claims from electrologists to the contrary, law in thirty-seven (37) states expressly prohibits them from performing laser hair removal without some form of medical supervision. In twelve (12) states, electrologists and cosmetologists are prohibited from performing laser hair removal under any circumstances. Fourteen (14) states require onsite medical supervision to laser hair removal performed by electrologists and cosmetologists, while eleven (11) other states require an initial medical examination and off-site medical supervision for laser hair removal procedures which are delegated to electrologists and cosmetologists. The issue of laser hair removal is not explicitly addressed in law in eight (8) states and the District of Columbia; however this is likely to change within the next few years. The District of Columbia is currently in the drafting stages of creating a definition of the practice of medicine which includes laser hair removal and other cosmetic medical procedures, and the Alaska Medical Board has issued a position statement which includes laser hair removal and other laser medical procedures within the definition of surgery.

Currently, only New York, Virginia, and Georgia currently explicitly exempt hair removal from consideration as the practice of medicine. New York’s exemption is based on a 1937 court case which exempts hair removal by any means from consideration as the practice of medicine. For your reference, I have attached a map and a chart which pertinent law in each state.

The same medical lasers used for hair removal are also used for other medical treatments. These lasers and intense-pulsed light devices which are utilized for hair removal can also be used for medical treatments such as skin rejuvenation, facial & leg vein treatments, fine line and wrinkle reduction, skin tightening, and vascular lesion treatments. The FDA allows these

prescription medical devices to be sold to those licensed by law to use or order the use of such device, as determined by the state. In the state of New York, where laser hair removal, unlike other laser procedures, is not considered a medical procedure, we have seen several incidences of electrologists and other non-medical professionals advertising the use of these devices for other laser medical procedures without physician oversight. We believe that expanding the scope of practice of electrologists to use these devices for hair removal opens the door to inappropriate expansion into other medical uses of lasers.

ASDSA has no objection to electrologists using “over-the-counter” laser hair removal devices. The FDA’s Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. When device manufacturers submit new devices for approval by the CDRH, the devices are classified as being for “prescription use” or “over-the-counter use” pursuant to the Code of Federal Regulations. Companies such as Altria, Spectra and others have developed laser hair removal devices which have been determined by the FDA as being “over-the-counter” and thus safe and appropriate for use by non-physicians.

Appropriate Medical Training & Physician Oversight for Non-ablative Laser Procedures Ensures Patient Safety

Specifically, we are concerned that non-ablative energy-based procedures, such as those utilizing intense pulsed-light, medical lasers, and radiofrequency devices, might be performed in Level II facilities without required on-site physician supervision. Even in the case of non-ablative procedures, complications can be severe. According to “Adverse Events Associated With Nonablative Cutaneous Laser, Radiofrequency, and Light-Based Devices,” (*Seminars in Cutaneous Medicine and Surgery*, Volume 26, Issue 1. , March 2007, Pages 15-21), “Dyspigmentation, blistering, and even scarring may also occur and are more common in patients with darker skin types, a suntan, or when lasers in the red spectrum are used.”

These procedures include but are not limited to the removal of vascular lesions, the removal of benign pigmented lesions, tattoo removal, photoepilation, and hair removal. While non-physicians may be trained on how to use a laser, they are not trained to recognize differing skin types, conditions, and diseases. According to a study published in the *Skin Therapy Letter*, “It is a truism in cutaneous laser therapy that firing a laser hand piece may be the least important portion of the treatment; it is everything but the actual treatment, including patient selection, parameter selection, and recognition and management of undesirable outcomes, that requires judgment and training.”

As stated in the article from *Seminars in Cutaneous Medicine and Surgery*, “Importantly, many laser practitioners are not dermatologists and may erroneously treat a pigmented lesion that is in fact a melanoma, pigmented basal cell carcinoma, or atypical nevus. A laser practitioner should be aware of the potential for misdiagnosis of malignant skin lesions and the necessity of dermatologic evaluation of pigmented lesions.”

An enclosed article documents the experience of a Colorado woman who received four medical laser treatments by a licensed Registered Nurse without physician supervision, before going to her physician to learn that the “brown sunspot” on her face was actually a melanoma, the most fatal skin cancer. Other articles and photos enclosed demonstrate the experience of patients

who were treated with the wrong lasers or lasers set at the wrong fluence for their skin type or condition, leaving them with painful burns and in some cases, permanent scarring.

For these reasons, in the interest of patient safety, ASDSA requests the Joint Committee on Public Health to vote down SB 836 as it is currently written. Thank you for your consideration. Should you have any questions, or wish to discuss this issue further, please do not hesitate to contact Director of Advocacy and Public Policy Lisle Poulsen at (847) 956-9126 or lpoulsen@asds.net.

Sincerely,



Robert A. Weiss, MD
President

cc: Jeffrey Dover, MD, FRCPC, President-Elect
Richard G. Bennett, MD, Vice President
David Goldberg, MD, JD, Secretary
Christopher J. Arpey, MD, Treasurer
Darrell S. Rigel, MD, Immediate Past President
Lawrence J. Green, MD, Scope of Practice Chair
Katherine J. Svedman, CAE, Executive Director
Lisle Poulsen, Director of Advocacy and Public Policy
Martin Cohn, Associate Director, Massachusetts Academy of Dermatology
Senator Joan M. Menard
Joint Committee on Public Health