















April 30, 2015

The Honorable Richard Devlin
The Honorable Peter Buckley
Oregon Joint Committee on Ways and Means
900 Court St. NE, Room H-178,
Salem, OR 97301

## Dear Chairmen Devlin and Buckley:

On behalf of the undersigned organizations, we strongly urge members of the Joint Committee on Ways and Means Committee to amend HB 2642, which sets forth requirements for estheticians to practice medicine (i.e. perform advanced non-ablative procedures) and creates the Board of Certified Advanced Estheticians within the Health Licensing Office. Together, as medical organizations, our utmost concerns are patient care and patient safety. Quality patient care is rooted in evaluating a patient's needs and current condition(s), selecting an appropriate course of treatment, and providing adequate information and follow-up care.

While we appreciate the work done to-date as evidenced by the already adopted amendments, including a clarification that non-ablative does not result in the wounding of skin or underlying tissue, and the deletion of "laser peel, laser vaporization and lasabrasion; skin needling through acupuncture; vein reduction; pigment lentigo reduction; acne reduction" from the list of advanced non-ablative esthetics procedures, we strongly caution the committee against advancing this bill any further without incorporating language that will address the patient safety concerns set forth below. As written, HB 2642 would create a public health hazard due to the minimal education and training requirements required to perform the procedures and lack of oversight of the certified advanced estheticians by a health care provider (MD, DO, PA or NP). These devices can cause profound skin injury, even when used at the manufacturer's recommended settings. Therefore, these devices can easily lead to injury (ablation or destruction) of all layers of the skin and underlying structures.

## Legislation Lacks Necessary Education and Training to Ensure Patient Safety

Short term, basic training that is set forth in HB 2642 to perform advanced non-ablative esthetic procedures is in no way equivalent to the training needed to understand the use of lasers or use of many other devices used for such procedures performed on the skin or hair, and its implications for each patient. Patient safety and quality of care will be seriously compromised.

Physicians, who complete a rigorous undergraduate academic curriculum, four years of medical school, 3-7 years of residency, and 12,000-16,000 hours of patient care training, have extensive education and training that enables them to recognize an immediate adverse response to non-ablative treatments, such as tissue whitening or graying. Such responses may indicate thermal injury, which would require immediate discontinuation of treatment. Even with such training, some complications associated with some of the procedures listed above may not be as predictable or evident by observing immediate tissue reactions. Further, adverse events may occur due to device malfunction or failure. Individuals operating such devices must be aware of this potential source of error.

In comparison to physicians, certified advanced estheticians are only required to have 500 hours as a laser operator under the supervision of a health care professional; or 40 hours of education related to laser theory and fundamentals and complete 24 hours of practical experience, according to this legislation. The American Society for Laser Medicine and Surgery (ASLMS) notes that only licensed medical professionals who have been trained appropriately in laser physics, tissue interactions, 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 precepted 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."

## Lack of Sufficient Oversight by a Health Care Provider

An initial skin exam by a health care provider is critical to patient safety. Laser and light-based devices have the ability to alter the pathology of skin cancer, rendering it either undetectable or causing a late diagnosis. Patient factors can significantly affect the outcome of procedures using lasers, including the patient's intrinsic background pigmentation and presence of a tan or other skin coloration change, planned outdoor activities, and patient's family and medical history. Infections or vascular abnormalities may be contraindications. A review of the patient's medication list and allergies must be completed to avoid possible complications. Finally, it should be determined if the patient has had any previous cosmetic surgeries or other procedures that could interfere with the treatment or alter tissue response.<sup>2</sup>

For these reasons, we believe it is essential that the committee include provisions requiring an initial patient exam by a health care provider and to require that the agreement set forth in Section 6(2)(c) is between a certified advanced esthetician and physician who has experience and training in advanced non-ablative procedures.

## **Evidence of Increased Injury by Non-Physicians**

A 2013 study demonstrates that there has been a recent rapid increase in malpractice claims filed against non-physician operators, particularly for botched cosmetic procedures.<sup>3</sup> A study of claims from 1999-2012 related to cutaneous laser surgery found that 42% of the cases involved a non-physician operator. From 2004 to 2012, a trend was observed toward an increased proportion of lawsuits stemming from cutaneous laser surgery performed by non-physicians. This trend is most notable from 2008 to 2011, during which time the percentage of cases involving a non-physician increased from 36% to 77%.<sup>4</sup>

Additionally, 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

<sup>&</sup>lt;sup>1</sup> Web, American Society for Laser Medicine and Surgery Educational Recommendations for Laser Use by Non-Physicians. www.aslms.org/public/standardserInp.shtml

<sup>&</sup>lt;sup>2</sup> Dawson, E. Willey A., Lee K. (2006, December 3). Adverse Events Associated With Nonablative Cutaneous Laser, Radiofrequency, and Light-Based Devices. *Semin Cutan Med Surg* 26:15-21.

<sup>&</sup>lt;sup>3</sup> Jalian H. R., Avram, M.(2013,October 16). Increased Risk of Litigation Associated With Laser Surgery by Nonphysician Operators. *JAMA Dermatol*.doi:10.1001/jamadermatol.2013.7117.

<sup>4</sup> Id.

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). We have also included as Exhibit B, photos of injuries resulting from the use of lasers.

Because there has been a significant increase in malpractice claims filed against non-physicians, it is likely that this will occur in Oregon should this legislation be enacted in its current version. It is imperative for patient safety that consumers understand the risks involved with cosmetic medical procedures and the qualifications of the individuals performing the procedure.

In addition to our proposed amendments to the oversight and education requirements, we urge the committee to include an additional amendment that would ensure the patient receive verbal and written information concerning the professional liability insurance of the certified advance esthetician and health care provider who has entered into agreement with the certified advanced esthetician. The language proposed in the current version would require professional liability insurance to be disclosed in the client disclosure form, but it is essential that such information be discussed verbally.

We appreciate the opportunity to provide written comments on this important public health issue. In order to protect the citizens of Oregon from adverse events and to ensure quality care, the undersigned urge members of the Joint Committee on Ways and Means to amend HB 2642 to address the critical patient safety concerns we have outlined above. For further information, please contact Lisa Albany, Associate Director of State Policy for the AADA, at <a href="LAlbany@aad.org">LAlbany@aad.org</a> or (202) 712-2615 or Kristin Hellquist, Director of Federal Advocacy & Practice Support, at <a href="khellquist@asds.net">khellquist@asds.net</a> or (847) 956-9144 for the ASDSA, as staff representatives to the coalition effort.

Sincerely,

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cc: Members, Joint Committee on Ways and Means Cournti Dresser, Oregon Medical Association