January 24, 2014

Ms. Sharon Wiser, Vice Chair
Oregon Board of Cosmetology
Oregon Health Licensing Agency (OH LA)
700 Summer St, NE, Suite 320
Salem, Oregon 97301-1287

Re: The Use of Lasers by Certified Estheticians

Dear Vice Chair Wiser and Members of the Oregon Board of Cosmetology:

As President of the American Society for Dermatologic Surgery Association (ASDSA), a surgical specialty organization representing over 5,800 physician members, I want to thank you for the opportunity to provide comment about the use of lasers by certified estheticians.

The ASDSA is concerned that allowing Certified Estheticians to perform laser medical procedures would jeopardize patient safety and disregard adequate and appropriate medical training. While these lasers are extremely safe and effective when used by medical professionals with appropriate training and oversight, in the wrong hands they can cause painful burns and permanent scarring.

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. Short term, basic training is in no way equivalent to a physician’s training and understanding of a medical procedure and its implications for each patient. Ultimately, patient safety and quality of care are seriously compromised.

Laser hair removal causes more complications than any other medical laser treatment. According to a study published in *Skin and Aging*¹, 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 the face (22%) and neck (12%). Physicians performing these procedures have years of training in residencies to medically recognize and address complications, in addition to evaluating the patient to determine the most appropriate treatment. For example, laser hair removal procedures are less effective on individuals with light-colored hair, and those with tanned or dark skin may be more susceptible to burning. With multiple medical laser devices available on the market, and as more and more devices become available, it is critical to ensure that patient safety remains the primary objective. The ASDSA feels strongly that cosmetic medical procedures, such as hair and tattoo removal, resurfacing, and other procedures using energy-based devices capable of damaging living

tissue, are more safely performed in a dermatologist’s office by the physician or under direct, on-site supervision of the physician.

As reported in the National Law Journal, laser hair removal has recently become a “hot spot” for litigation, leading to costly and prolonged lawsuits. According to the article, “Laser hair removal in particular is triggering lawsuits, lawyers note, warning that even more litigation is on the horizon as the number of medical spas soars... In Arizona, a woman recently sued a spa in state court, alleging she was ‘severely burned and scarred’ during laser hair removal. Also in Arizona state court, a man in sued a spa over scarring, ‘extreme pain’ and burning he allegedly suffered from laser hair removal on his back and shoulders.” According to a study published the Journal of the Medical Association, the percentage of medical malpractice lawsuits involving the non-physician use of medical lasers has grown steadily over the past four years, from just 38 percent of lawsuits in 2008 to 76 percent of lawsuits in 2011. Perhaps most relevant is the fact that according to this same data, 89 percent of laser hair removal-related medical malpractice lawsuits in the year 2011 involved non-physicians performing laser hair removal.

The 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...” As such, use of these devices should be considered the practice of medicine, and should not occur outside the supervision of a licensed and appropriately trained physician.

Any procedure which utilizes energy-based devices capable of damaging living tissue performed on human beings for cutaneous conditions should be considered as the practice of medicine.

Consideration of the use of medical lasers 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 below.

H-475.983 Definition of Surgery
Our AMA adopts the following definition of "surgery" from American College of Surgeons Statement ST-11:

Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means.

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Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system also is considered to be surgery (this does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel. Patient safety and quality of care are paramount and, therefore, patients should be assured that individuals who perform these types of surgery are licensed physicians (defined as doctors of medicine or osteopathy) who meet appropriate professional standards. (Res. 212; A-07)

H-475.989 Laser Surgery
Our AMA (1) adopts the policy that laser surgery should be performed only by individuals licensed to practice medicine and surgery or by those categories of practitioners currently licensed by the state to perform surgical services; and (2) encourages state medical associations to support state legislation and rulemaking in support of this policy. (Sub. Res. 39, I-90; Reaffirmed: Sunset Report, I-00)

H-475.988 Laser Surgery
The AMA supports the position that revision, destruction, incision or other structural alteration of human tissue using laser is surgery. (Res. 316, A-96; Reaffirmed: CSAPH Rep. 3, A-06)

Moreover, it is important to consider that in addition to the use of medical lasers themselves, some procedures, such as laser hair removal, also require the use of a medical-grade topical anesthetic. In at least two cases, the dispersion of this anesthetic without appropriate supervision has resulted in patient deaths. In 2007, and again in 2009, the Food and Drug Administration (FDA) issued public advisories cautioning consumers about this issue. As stated in the advisory, "FDA is aware of two instances where women, aged 22 and 25 years old, applied topical anesthetics to their legs to lessen the pain of laser hair removal. These women then wrapped their legs in plastic wrap, as they were instructed, to increase the creams' numbing effect. Both women had seizures, fell into comas, and subsequently died from the toxic effects of the anesthetic drugs. The skin numbing creams used in these two cases were made in pharmacies and contained high amounts of the anesthetic drugs lidocaine and tetracaine. The FDA also has received reports of serious and life-threatening side effects such as irregular heartbeat, seizures and coma, and slowed or stopped breathing following the use of these numbing products. These effects happened in both children and adults and when the anesthetic drug was used both for approved and unapproved conditions."

For these reasons, we urge the Oregon Board of Cosmetology to reconsider allowing Certified Estheticians using medical laser devices. For your review, I am attaching our patient safety positions and position on the corporate practice of medicine. Thank you for your consideration. Should you have any questions or need further information, please do not hesitate to contact Director of Advocacy and Public Policy Lisle Soukup at lsoukup@asds.net or (847) 956-9126.

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Sincerely,

Mitchel P. Goldman, MD, President
American Society for Dermatologic Surgery Association

cc: George J. Hruza, MD, President-Elect
Timothy C. Flynn, MD, Immediate Past President
Naomi Lawrence, MD, Vice President
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Ken K. Lee, MD
Mary Olhausen, Executive Director, Oregon Dermatology Society
Position on the Practice of Medicine and the Delegation of Medical Procedures to Licensed Allied Health Professionals
The guiding principle for all dermatologic surgeons is to practice ethical medicine with the highest possible standards. Physicians should be properly trained in all procedures performed to ensure the highest level of patient care and safety. A physician should be fully qualified by residency training and preceptorship or appropriate course work. Training should include an extensive understanding of cutaneous medicine and surgery, the indications for each procedure, and the pre- and post-operative care involved in treatment. It is the position of the ASDSA that only active and properly licensed doctors of medicine and osteopathy shall supervise or engage in the practice of medicine.

Under the appropriate circumstances, a physician may delegate certain procedures to licensed allied health professionals. The physician must directly supervise the licensed allied health professionals to protect the best interests and welfare of each patient. The supervising physician shall be physically present on-site, immediately available, and able to respond promptly to any question or problem that may occur while the procedure is being performed. It is the responsible physician’s obligation to ensure that, with respect to each procedure performed, the licensed allied health professionals possess knowledge of cutaneous medicine, documented training in the procedure, the indications for the procedure, and the pre- and post-operative care involved.

Position on the Definition of the Practice of Medicine
The practice of medicine involves diagnosis, treatment, or correction of human conditions, ailments, diseases, injuries, or infirmities whether physical or mental, by any means, methods, devices, or instruments. The practice of medicine includes, but is not limited to:

a. Undertaking to perform any surgical operation upon any person; and

b. Performing any act or procedure that uses a biologic or synthetic material, or chemical application of any kind if it alters or damages or is capable of altering or damaging living tissue; and

c. Performing any act or procedure using a mechanical device, or displaced energy form of any kind if it damages or is capable of damaging 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. Living tissue is any layer below the dead cell layer (stratum corneum) of the epidermis. The epidermis, below the stratum corneum, and dermis are living tissue layers. Certain FDA-approved Class I and II devices, by their intended or improper use, can damage below the stratum corneum. Therefore, their use and the diagnosis and treatment surrounding their use, constitutes the practice of medicine.

Position on The Use of Energy Devices Capable of Damaging Living Tissue
Physicians shall be trained appropriately in the physics, safety, and surgical techniques involved in the use of energy devices capable of damaging living tissue prior to performing procedures

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using such devices. Living tissue is defined as any layer below the dead cell layer (stratum corneum) of the epidermis. Training should include an extensive understanding of cutaneous medicine and surgery, the indications for such surgical procedures, the pre- and post-operative care involved in treatment, as well as the treatment of complications associated with these devices.

A physician who delegates such procedures should be fully qualified by residency training and preceptorship or appropriate course work prior to delegating procedures to licensed allied health professionals and should directly supervise the procedures. The supervising physician shall be physically present on-site, immediately available, and able to respond promptly to any question or problem that may occur while the procedure is being performed.

Any licensed allied health professional employed and designated to perform a procedure by a physician must be under the direct, on-site supervision of the physician. For each procedure performed, the licensed allied health professional must have appropriate documented training in the physics, safety, and surgical techniques of each system. The licensed allied health professional should also be appropriately trained by the delegating physician in cutaneous medicine, the indications for such surgical procedures, and the pre- and post-operative care involved in treatment.

Position on the Use of Dermal Fillers and Injectables
The American Society for Dermatologic Surgery Association has become increasingly concerned about the proliferation of non-physicians practicing medicine and its impact on patient safety. Recent studies conducted by the ASDSA have shown an increase in patient complications resulting from this trend. As implantable devices, dermal fillers and botulinum toxins require extensive specialized physician knowledge to ensure the highest level of care. The precise placement of a needle for a botulinum toxin injection or the exact depth of administration of a filler is a specialized type of injection. Problems inherent with the technique are primarily problems encountered with the materials. Additionally, the tolerance for adverse events for these specialized injections of implantable devices is comparatively low to that of typical injections. As such, it is the position of the Association that only properly trained physicians should be injecting dermal fillers and botulinum toxins. Training should include an extensive understanding of cutaneous medicine and the aging face, knowledge of the various FDA-approved injectable products and their indications, experience in injection techniques appropriate to the products, and the pre- and post-procedure care involved in treatment.
Support:

- Bans on the practice of medicine in non-hospital facilities which are not at least fifty-one percent physician-owned in the state where the physician is licensed
- Medical decisions that are based on patient outcomes and quality of care
- Appropriate onsite physician supervision, oversight and training
- Adequate penalties for violation of the corporate practice of medicine bans

Oppose:

- Large corporately-owned medical spas hiring so-called “medical directors” to supervise “in name only”
- Decision-making based on financial gain
- The practice of renting one’s name and medical license in exchange for a monthly fee or percentage of profits
- Penalties which are paltry to the extent that the ban on the corporate practice of medicine becomes moot

In the interest of patient care and safety, the ASDSA supports the bans of the corporate practice of medicine. Laws prohibiting the corporate practice of medicine, for example, disallow a physician from acting as “medical director” of a spa, salon or other facility where cosmetic medical treatments are performed when the physician does not own the practice. ASDSA is gravely concerned with any proposed erosion of proven patient protections.

It should be noticed that the problem lies not with the medical spa model, itself, but rather with non-physician-owned medical spas that do not provide adequate physician supervision and oversight. There are many legitimate, safe, physician-owned medical spas that operate with a high standard of patient care. However, lack of regulation and enforcement has enabled a large number of medspas to offer cosmetic medical procedures by inadequately trained or supervised persons to an unsuspecting public.

Our Association has, on an ongoing basis, received a number of reports from our members who have been solicited to act as medical directors settings in name only, in a medical spa, or “medspa” in exchange for a monthly fee. We have become increasingly concerned about the proliferation of non-physicians practicing medicine and its impact on patient safety. Recent studies conducted by the ASDSA have shown an increase in patient complications resulting from this trend. A 2005 study of laser complications by non-physicians published in Skin and Aging magazine found that, “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.”

Financial incentives for performing medical procedures in a medical spa setting are inherent to the business model, which more closely represents a retail store than a medical practice. As stated in a 2007 *Skin Therapy Letter* article:

"Incentives for nonphysician providers to maximize revenue generation in a spa or thinly supervised setting can increase the risk of adverse events by:

- hurrying preoperative evaluation and laser treatment
- encouraging the treatment of patients who may be poor laser candidates.

"To the extent that nonphysician providers may have a skewed financial incentive structure, wherein they are more often rewarded for revenue generation than penalized for adverse events and patient dissatisfaction, the impetus to increase business may dominate. The result means greater risk for the patient, and for the ostensibly delegating but possibly off-site physician, who may have medico-legal responsibility for problems accruing from delegated services. Beyond adverse events, such incentives may lead to unnecessary treatments motivated by the desire to increase financial yield by extending the number of sessions. Indeed, more revenue may be generated by systematically undertreating patients to ensure that they return for more visits. Subtherapeutic treatments may also reduce the risk of adverse events when laser treatments are delivered by minimally trained nonphysician providers. While undertreatment is unlikely to cause irrevocable physical injury, it is a form of fraud that wastes patients’ time and money."2

The corporate practice of medicine business model carries a risk to physician autonomy in making the decisions for the best treatment of the patient when those decisions are contrary to the profitability of the corporation.

A California law passed in 2012 provides an excellent model with regard to appropriate penalties for violation of the corporate practice of medicine ban in medical spa facilities.3 The new law provides that when a business organization either employs a California physician, or contracts with him/her to serve as a “medical director” of a health care practice he/she does not own, and the business organization provides medical care that ordinarily can only be provided by the holder of a valid California medical license — actions already prohibited by California law — that conduct will be subject to penalties that are more proportionate to the risks to which patients are exposed, and more proportionate to the money of which they’re being defrauded.

Before stricter penalties were passed, medspa chains created business management and franchising schemes that violated the law. The too-common practice of lay-owned businesses hiring so-called medical directors was already prohibited but poorly enforced. Prior to the passage of this law, Joint Medical Board/Nursing Board hearings in 2007 concluded better enforcement is needed of existing California law that prohibits laypersons or corporate entities from owning any part of a medical practice.

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