December 6, 2019

Rita Chapin
PO Box 2018
Austin, TX 78768
Submitted electronically: rules.development@tmb.state.tx.us

Re: Proposed amendments to Rule §193.17 Nonsurgical Medical Cosmetic Procedures

Dear Ms. Chapin,

On behalf of the undersigned organizations, we appreciate the opportunity to comment on the amendments to Rule §193.17 Nonsurgical Medical Cosmetic Procedures. Patient safety is of utmost concern to us, and we applaud the Texas Medical Board for acknowledging the need for further oversight of facilities where these procedures are being performed; however, we are concerned that this proposal would authorize both advanced practice registered nurses (APRNs) and physician assistants (PAs) to supervise these procedures and does not ensure physicians and non-physicians who are performing medical cosmetic procedures are appropriately trained.

Our organizations believe that procedures using a Food and Drug Administration (FDA)-regulated device (mentioned in the definition of "prescription medical device") should only be performed by a physician or appropriately trained non-physician personnel under **the direct, onsite supervision of an appropriately trained physician**.[i] Procedures by any means, methods, devices or instruments that can alter or cause biologic change or damage the skin and subcutaneous tissue constitutes the practice of medicine, including the use of foreign or natural substances by injection or insertion. [ii,iii] Quality patient care also includes evaluating a patient's needs and condition(s), selecting an appropriate course of treatment and providing adequate follow-up care. This proposed rule jeopardizes patient safety and disregards what is considered adequate and appropriate medical education and training for the reasons set forth below.

An APRN or PA does not possess the knowledge or training to provide adequate care for a patient undergoing a medical procedure or how to handle adverse events. In order to gain the competence to accurately diagnose and prescribe treatment, a physician must undergo more than 10,000 hours of intense medical education and training. Without this vast level of training and experience, the safety of patients in Texas could be at risk. For optimum care, patients should have the opportunity to receive a proper examination by an appropriately trained and licensed physician and follow-up care by a physician assistant or nurse practitioner under the direct, on-site supervision of a qualified, licensed physician. It is in the best interest of patients that they be aware of who is providing their care. A licensed physician should be on site so that they can be notified and immediately provide support to the patient to handle any patient complaints, complications, side effects or adjustment of treatment parameters due to unique or unexpected patient tissue response to treatment.

Further, the supervising physician must not delegate procedures outside of their original area of practice unless he or she can demonstrate adequate training, competence, and experience. Training programs provided by a manufacturer or vendor of a medical device or supplies must not be the supervising physician's only education in the service or operation of the medical device or supplies to be used. We recommend that the supervising physician complete an Accreditation Council for Continuing Medical Education (ACCME) or American Osteopathic Association (AOA)-approved continuing education, or Accreditation Council for Graduate Medical Education (ACGME) or AOA-accredited postgraduate program that includes training in the medical procedure, including cosmetic medical procedure, performed. The AACME continuing education program must meet Category I AMA approval.

An analysis by the FDA's General and Plastic Surgery Devices Panel of six years of adverse event reports associated with the use of injectable dermal fillers, which are included in the Rule's definition of "administer," concluded the following: there are a number of adverse events that are serious and unexpected, such as facial, lip and eye palsy, disfigurement, retinal vascular occlusion, blindness, as well as rare but life-threatening events such as severe allergic reactions and anaphylactic shock.

- Some of the common adverse events that are expected to occur shortly after injection and resolve quickly can have a delayed onset and/or remain for a long period of time and turn into more serious problems.
- A number of the adverse events reported to the FDA and the device manufacturers imply that, in these cases, the administration of injectables were performed by untrained personnel or in settings other than health clinics or doctors' offices.[iv]

With regards to dermal fillers, a survey conducted by the Physicians Coalition for Injectable Safety found that 84 percent of physician respondents had seen at least one patient with complications from cosmetic injectables and 38 percent had seen complications arising from cosmetic injections administered by an unqualified or untrained provider.[v] Injectable fillers that are approved for injection in the dermis or mid-to-deep dermis require extensive knowledge of facial anatomy to ensure proper placement of the injections. Understanding which injectable product is appropriate for each anatomic site and its particular limitations is fundamental to avoiding adverse effects. In discussing these devices, the FDA's Consumer Health Information materials suggest that patients should discuss fillers with a doctor who can refer the patient to a specialist in the field of dermatology.[vi]

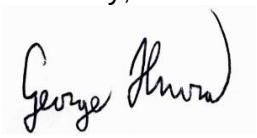
Growing evidence demonstrates that adverse outcomes are occurring more frequently as the cosmetic industry is growing and more of these procedures are performed by non-physicians. The number of lawsuits filed against non-physicians — including registered nurses (RNs), nurse practitioners (NPs), and aestheticians or technicians — performing cutaneous laser surgery has more than doubled in recent years. From 2008 to 2011, the percentage of laser-related cases that involved a procedure by a non-physician, largely involving laser hair removal, jumped from 36 percent to nearly 78 percent. While only one-third of laser hair removal procedures are performed by non-physicians, such procedures account for nearly 76 percent of all lawsuits from 2004 to 2012. Additionally, 64 percent of cases involving non-physicians involved a spa from 1999 to 2012, with the figure rising to nearly 77 percent from 2008 to 2012. Cases

involving non-physicians in a physician office fell from a third of cases in the same time period to 23.4 percent from 2008 to 2012.[vii]

Lastly, the proposal would define these procedures as "nonsurgical"; however, we urge you to reconsider the definition of surgery to include 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. **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**.[viii]

In order to protect the people of Texas from adverse events resulting from cosmetic medical procedures and to ensure quality care, **we urge the Board to amend the language to require the direct on-site supervision of a physician and to set forth more stringent training requirements.** Only appropriately trained providers, or those working under the direct, on-site supervision of a physician, should be able to perform any procedures that constitute the practice of medicine or surgery. Should you have any questions, please contact Emily Besser, ASDSA Manager of Advocacy and Practice Affairs, at *ebsser@asds.net* or at (847) 956-9121.

Sincerely,



George J. Hruza, MD, MBA, FAAD
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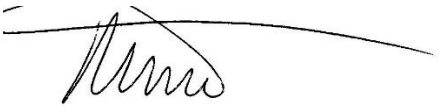

Marc D. Brown, MD
President
American Society for Dermatologic Surgery Association

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[i] ASDSA *Position Statement on Delegation*. http://asdsa.asds.net/uploadedFiles/ASDSA/Policymakers/ASDSA-%20Delegation%20Position%20Statement(4).pdf

[ii] ASDSA *Position Statement on the Practice of Medicine.* http://asdsa.asds.net/uploadedFiles/ASDSA/Policymakers/ASDSA-Definition%20of%20the%20Practice%20of%20Medicine.pdf

[iii] AADA *Position Statement on Medical Spa Standards of Practice*. https://www.aad.org/Forms/Policies/Uploads/PS/PS-Medical%20Spa%20Standards%20of%20Practice.pdf

[iv] https://www.inlandcosmetic.com/wp-content/uploads/2008/11/2008-4391b1-01-FDA-Executive-Summary-Dermal-Fillers.pdf

[v] New Data Finds Greater Measures Needed For Consumer Safety And Education On Injectable Therapies. August 15 2007. Retrieved from http://legacy.aafprs.org/media/press_release/150807.htm

[vi] Filling in Wrinkles Safely. Retrieved from https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049349.htm

[vii] April 2014 issue of *JAMA Dermatology* (*JAMA Dermatol*. 2014;150(4):407-411. doi:10.1001/jamadermatol.2013.7117)

[viii] Definition of surgery (2007). Retrieved Nov. 1, 2017. https://policysearch.ama-assn.org/policyfinder/detail/surgery?uri=%2FAMADoc%2FHOD.xml-0-4317.xml