29 January 2018

The Honorable Judge Jeff Oxley
Administrative Law Judge
Minnesota Office of Administrative Hearings
Attn: Ms. Katie Lin
P.O. Box 64620
St. Paul, MN 55164-0620

via facsimile: 651-539-0310

RE: Comments regarding the Minnesota Board of Cosmetology Examiner's Proposed Adopted Permanent Rules Relating to Licensing Advanced Practice Estheticians (Draft dated 12/15/2017, Revisor, SS/JU, AR4342)

Dear Honorable Judge Oxley,

As a member of the medical community of the State of Minnesota, I appreciate the opportunity to submit the following comments on the Minnesota Board of Cosmetology Examiner's (BCE's) Adopted Permanent Rules Relating to Licensing Advanced Practice Estheticians (APE) (Draft dated 12/15/2017, Revisor, SS/JU, AR4342), which have been proposed by the BCE pursuant to revised Minnesota Laws 2015, chapter 77, article 2, sections 31 and 48. I note that the creation of this new APE license by the BCE necessitated redefinition of the "basic" Esthetician license, which already existed. I also appreciate the opportunity to participate personally in the rule making process as a member of the Advisory Committee on Advanced Practice Esthetics (ACAPE), while I held the office of President of the Minnesota Dermatological Society.

I recognize that the above statutory changes have passed into law. My purpose is both to protect patient safety and to reduce the risk that the advanced practice esthetician (APE) licensee might harm his or her clients and might inadvertently practice medicine. As currently drafted, the rules are both arbitrary and an unhelpful guide for a practicing APE. I believe that they do not provide adequate practical guidance for APEs nor do they provide sufficient protection for clients undergoing treatment by APEs. The recommendations I make below are designed to reduce, but cannot completely eliminate, the chance that APE-provided cosmetic treatments would extend through the dermal epidermal junction (DEJ) and into the dermis. Minnesota statutes only permit the APE to perform treatments that affect the epidermis. Treatments that extend beyond the epidermis violate the same statue and would constitute the practice of medicine.

Concern 1: Scope of Practice Conflicts with the Practice of Medicine
I wish to point out that there is clear conflict of this new definition of advanced practice esthetics with the definition of the practice of medicine.
In Minnesota, a person is practicing medicine if the person does any of the following: "offers or undertakes to prevent or to diagnose, ***correct, or treat in any manner or by any means***, ***methods, devices, or instrumentalities***, any disease, illness, pain, wound, fracture, infirmity, ***deformity or defect*** of any person" (3) or "offers or undertakes to perform any surgical operation including ***any invasive or noninvasive procedures involving the use of a laser or laser assisted device***, upon any person" (4) (Minnesota Statutes 147.081, Subd. 3). This definition clearly includes cosmetic treatment of the skin or any part of the body.
Under the proposed rules, the practice of esthiology is "the cosmetic treatment of the stratum corneum of the epidermal layer of the skin surface" and "estheticians must not use any tool or equipment designed to penetrate beyond the stratum corneum of the epidermis" (2105.0105, Subp. 2). Under the same proposed rules, the practice of advanced practice (AP) esthetics is "the cosmetic treatment of the epidermal layer of the skin" and "AP estheticians must not use any tool or implement designed to penetrate beyond the epidermal dermal juncture" (2105.0105, Subp 5). Practicing under these definitions, both estheticians and APEs could be seen as practicing medicine.

Concern 2: Definitions (2105.0010) and Scope of Practice definition (2105.0105)
I feel it is critical that the proposed rules include clear definitions for the defining skin structures used to define scope of practice. We would propose the following terms and definitions be added to the current proposed rules:

Stratum corneum. The "stratum corneum" is the most superficial anatomic layer of the epidermis. It is a non-viable structure composed of cells and lipids which acts as a barrier to microbes and chemical entry, but also to prevent water loss. The stratum corneum measures 0.01-0.02 millimeters in thickness.

Epidermis. The "epidermis" is the anatomic layer of the skin which covers and protects the human body, comprised, in order from superficial to deep, of four sublayers, the stratum corneum, stratum granulosum, stratum spinosum, and stratum basale. Excepting the stratum corneum, the epidermis is composed of living cells. The epidermis measures approximately 0.1 millimeters in thickness.

Dermal Epidermal Junction. The "dermal epidermal junction" (DEJ) is the anatomic layer of the skin found between the epidermis and dermis. Since the DEJ connects the epidermis to the dermis, the DEJ is critical to the adherence of the skin to the human body. Disruption or injury of the DEJ creates a wound which may cause scar formation.

Dermis. The “dermis” is the viable anatomic layer of the skin found below the dermal epidermal junction. Disruption or injury of the dermis creates a wound which causes scar formation.

I recommend that the following definition be altered as indicated:

Advanced exfoliation. “Advanced exfoliation” means a cosmetic procedure… to partially ~~or completely~~ remove the epidermis through manual, mechanical, or chemical means.

This change would solve the concern regarding total epidermal removal, which is not usually intended to occur in esthetics in practice. It also helps to solve the concern brought forth during the January 8, 2018 public hearing regarding the degree or amount of the epidermis which would be injured in a given cosmetic treatment session. By using the term “partially” alone, and deleting “completely” there would be no room for misinterpretation that the whole epidermal surface could be treated. This point would also be best addressed by restricting the amount of body surface area allowed to be treated in one treatment session (see below).

I also recommend that the following Scope of Practice definition be altered as indicated:

Advanced practice esthetic services. The practice of advanced practice (AP) esthetics is the cosmetic treatment of the epidermal layer of the skin. AP estheticians must not use any tool or implement **in a manner intended** ~~designed~~ to penetrate beyond the epidermal dermal juncture” (2105.0105, Subp 5).

This change would solve the issue brought forth in the January 8, 2018 hearing regarding the manner of use of devices which could be used to penetrate the skin, but are most commonly used in a manner which is not intended to do so; for example, use of a scalpel blade for dermaplaning rather than incising the skin.

Concern 3: Regarding the depth and degree of injury

Statute defined APE as “a person who for compensation performs personal services for the cosmetic care of the skin, including the use of mechanical or electrical skin care apparatuses or appliances that are used on the epidermal layer of the skin” (Minnesota Statutes 155A.23, Ch 77, Art 2, Section 31, Subd 14. Effective August 1, 2015). This effectively limits any impact of cosmetic treatment rendered by an APE to the epidermis itself and, given the definition of the practice of medicine, makes any cosmetic treatment impacting the dermis out of bounds. Since this boundary is clearly defined by statute, the resulting regulations may not allow a licensee to use any method of cosmetic treatment

which impacts the dermis in any way. Unfortunately, the proposed rules would allow a licensee to treat the epidermis in ways which would be expected to affect the dermis.

During ACAPE deliberations, an attempt was made to characterize and limit the effects of an APE's treatment by intent, by the nature of the injury, and by depth. That is, a basic esthetician license would allow the licensee to intend to treat the superficial most layer of the epidermis, the statum corneum alone; APE's would be allowed to intend to treat the full thickness epidermis, composed of the strata corneum, granulosum, spinosum, and basale, but must leave the dermo-epidermal junction and subtending dermis intact.

An issue not discussed by the ACAPE and which has not been defined by the proposed rules, is the amount of body surface area (BSA) of total epidermal injury which would be allowable. As pointed out in the January 8, 2018 rules hearing by Dr. Cynthia Schlick, this parameter is every bit as important as depth of injury. Full thickness epidermal injury may be likened to a burn. The larger the BSA of injury the greater the risk to the patient. Changing the definition of "advanced exfoliation" as mentioned above and limiting the allowable BSA for cosmetic treatment would provide a significant patient safety parameter for APEs. I propose that the allowable BSA which may be treated in one session to epidermal injury by an APE be set at 3%, approximately the BSA of the face.

Again, in the ACAPE discussions, the nature of treatment injury was suggested to mean physical or biochemical injury to the cells of the stratum corneum or the epidermis. Such a definition would still allow use of low level light therapy or other treatment modalities which may alter tissue function, but without creating an injury which would necessitate a wound healing response. Unfortunately, this important point was left out of the currently proposed rules.

I have previously proposed limiting the mechanism of injury allowable under the proposed rules. In order to control the depth and degree of cosmetic treatment injury, we feel strongly that specific limitations should be set regarding the use of chemical peels, lasers and non-laser light sources, and other electrical energy devices which might be used by APEs.

Our specific recommendations are as follows:

a) Use of lasers, by definition (see above), falls squarely within the practice of medicine and would not be allowed to be used by estheticians or APEs. Thus, we agree with the proposed rules which prohibit laser use by estheticians and APEs. Intense pulsed light (IPL) devices are just as potentially dangerous as lasers and carry an ANSI Class IV designation. As such, we propose that the proposed rules include a specific prohibition against use of IPLs.
b) For other non-laser light devices, radiofrequency devices, and ultrasound devices: FDA Class I Medical Devices would be permitted. All other devices should be excluded. The rationale for this recommendation is that many electrical energy devices have injurious effects which extend well beyond the epidermis and into the dermis.
c) Chemical peels. The depth of penetration of a chemical peel solution is based on peel solution's characteristics, notably the chemical composition and concentration, as well as patient characteristics, notably skin thickness at the site of application, skin type, underlying disease states, and skin barrier status. While there is no codifiable method to absolutely ensure that a peel remains above the DEJ, certain criteria may minimize, but not eliminate, the chance that a peeling solution's effect will penetrate beyond the DEJ. Based upon the medical literature, we propose as acceptable the following peeling solution chemical compositions and strengths at no more than: salicylic acid and other beta hydroxy acids (14%), glycolic acid and other alpha hydroxy acids (<30%), tricholoracetic acid (<10%), Jessner's solution, and its individual constituent agents, resorcinol, lactic acid, and salicylic acid, at 14% each. Use of phenol and modified phenol solutions should be prohibited. Combination peels of allowable agents may be permissible if the concentration of active peeling agent does not exclude any of these limits, though we note that combination peels may often extend far beyond the depth of any individual peeling ingredient alone.

Defining intent in the language of proposed rules does make perfect sense if there are "bright lines" which may not be crossed. Once a bright line is established; for example, not to exceed the use of 30% glycolic acid in performing a chemical peel, then the use of a higher concentration would indicate an intent by the practitioner to exceed their scope of practice, and penalties would be invoked.

Concern 4. Skin needling, AKA skin penning (2105.0105, Subp. 5, C)
It should be clearly understood that skin needling is like tattooing without the ink. In tattooing, the tattoo machine delivers pigment into the dermis. This fact was discussed and agreed to by the members of the ACAPE. Since ink or indelible pigments are not used in this technique, and because APEs practice is limited to cosmetic treatment of the epidermis only, skin needling practice does not fall under the purview of Body Arts regulation in the State of Minnesota. The depth of skin needling by APEs must be limited in the proposed rules to 0.1 millimeter, complying with the known epidermal thickness and the limitation of APE practice to the epidermis. In addition, because skin needling is an essentially identical technique to tattooing, those who do practice skin needling should be held to the same Health and Safety, as well as Professional, standards as licensed Minnesota tattoo artists (Minnesota Statutes 146B.06 and 146b.07, respectively).

An additional concern is the use of various topical products whose constituents would be driven into the skin during skin needling. Such a practice would constitute the delivery of metabolically active compounds into the body into and through the epidermis. These compounds would then act as drugs with very different effects than when they are safely applied topically to intact skin. Furthermore, topical agents applied to skin which has been treated with skin needling can and do enter the epidermis through the perforations created during skin needling. Thus, skin needling is a potential method of drug delivery into the human body. As such, use of anything other than sterile normal saline or sterile water prior to, during, or after skin needling must not be allowed under the proposed rules and should be included as an Unregulated Service (2105.0010, Subp. 13).

Concern 5: Wound healing education
The proposed rules, indeed the pre-existing statutes, allow for licensees to create injury to the skin, but do not mandate that estheticians gain an understanding that such injuries create wounds, which then must be managed. Physicians are trained to manage wounds, but cosmetologists and estheticians under existing curricula are not. In the most commonly used aesthetics textbook, Gerson et al's *Milady Standard Esthetics: Fundamentals* (11e), there is virtually no content to educate the reader on the topic of wound healing and wound management. I propose that specific education on wound healing and wound management be included in the APE curricula which will be developed pursuant to the acceptance of the finalized proposed rules.

Concern 6: Absence of penalties for violating rules.
The proposed rules do not address investigation and punishment for those violating the proposed rules. Appropriate penalties should be clearly indicated.

Thank you for your consideration of our concerns in modifying the proposed rules.

Respectfully submitted,

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Former President, Minnesota Dermatological Society
President, Academic Dermatology, PC