Response to Regulation of laser services, H.F. 1529, Abler, Questionnaire

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1. ***How is this profession's scope of practice in the area of proposed change currently defined and what failings or shortcomings are being addressed by the proposed changes to the profession's scope?***

Re: HF 1529, "Sec. 2. Minnesota Statutes 2012, section 147.081, subdivision 3, is amended to read:"

Contrary to claims by the sponsors of HF 1529 the use of medical lasers, are, indeed, regulated by the State of Minnesota.

Under 2013 Minnesota Statutes §147.081, Practicing Without License; Penalty:

Subd. 3. Practice of medicine defined (my emphasis), "For purposes of this chapter, a person not exempted under section §147.09 is "practicing medicine" or engaged in the "practice of medicine" if the person does any of the following:

(1) advertises, holds out to the public, or represents in any manner that the person is authorized to practice medicine in this state;

(2) offers or undertakes to prescribe, give, or administer any drug or medicine for the use of another;

(3) 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;

(4) 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;

(5) offers to undertake to use hypnosis for the treatment or relief of any wound, fracture, or bodily injury, infirmity, or disease; or

(6) uses in the conduct of any occupation or profession pertaining to the diagnosis of human disease or conditions, the designation "doctor of medicine," "medical doctor," "doctor of osteopathy," "osteopath," "osteopathic physician," "physician," "surgeon," "M.D.," "D.O.," or any combination of these designations."

The use of medical lasers are further addressed within 2013 Minnesota Statutes § 147E.05, which explicitly prohibits naturopaths from using medical lasers, "A naturopathic doctor registered under this chapter shall not perform surgical procedures using a laser device or perform surgical procedures beyond superficial tissue."

Re: Section 1. [144.6586] Health Care Advertising Transparency

The contention by proponents of HF 1529 that this section has identical language to that which was proposed in 2011 (HF1225/SF707) is only partially accurate. That bill went through several iterations, most notably:

- The following language was not contained in the final iteration of our 2011-2012 bill: "a) An advertisement for health care services that includes a health care provider's name shall identify the title and type of license the health care provider holds under which the health care provider is practicing." This section is unnecessary, as existing 2013 Minnesota Statutes §144.6585 Identification of Health Care Providers already requires the following:

  "Any health care provider who is licensed, credentialed, or registered by a health-related licensing board as defined under section 214.01, subdivision 2, must wear a name tag that indicates by words, letters, abbreviations, or insignia the profession or occupation of the individual."

  "The name tag must be worn whenever the health care provider is rendering health services to a patient, unless wearing the name tag would create a safety or health risk to the patient. The failure to wear a name tag is not reportable under chapter 214."

- Under proposed language in HF 1529, and in contrast to our 2011-2012 bill, the section regarding board certification disclosure for physicians, fails to provide any recourse for osteopathic physicians board certified by the American Osteopathic Association (AOA) to claim board certification. This is a significant oversight that could potentially affect the 600 osteopathic physicians providing care to Minnesota patients (177 of which are currently AOA board certified and would not be able to advertise this widely recognized qualification under the current proposal). AOA board certified physicians who have completed legitimate, accredited specialty training and met all requirements for board certification for which they should be able to include in public communications and advertisements.

- Additionally, the language with regard to board certification disclosure for physicians has evolved significantly since the bill's introduction. Perhaps most notably, The currently-agreed upon language by the American Medical Association, the American Society of Plastic Surgeons, the American Academy of Dermatology Association, the American Academy of Facial Plastic and Reconstructive Surgery, the American College of Emergency Physicians, the American Osteopathic Association, the American Academy of Orthopaedic Surgeons, American Academy of Facial Plastic and Reconstructive Surgery and the American Academy of Ophthalmology is as follows: "A medical doctor or doctor of osteopathic medicine may not hold oneself out to the public in any manner as being certified by a public or private board including but not limited to a multidisciplinary board or "board certified," unless all of the following criteria are satisfied:
  (a) The advertisement states the full name of the certifying board.
  (b) The board either:
  1. Is a member board of the American Board of Medical Specialties (ABMS) or the American Osteopathic Association (AOA).
  2. Requires successful completion of a postgraduate training program approved by the Accreditation Commission for Graduate Medical Education (ACGME) or the AOA that provides complete training in the specialty or subspecialty certified, followed by prerequisite certification by

the ABMS or AOA board for that training field and further successful completion of examination in the specialty or subspecialty certified

- Finally, even the above-agreed upon language is evolving. The coalition involved in developing the agreed-upon language above is meeting again shortly to ensure that the language is consistent with recent educational/training developments. For this reason, and because the laser provision section of this bill is harmful and misleading, as described in the rest of this document, we are recommending an outright oppose on HF 1529 rather than requesting amendments.

2. Does specialized skill or training support the expansion of this occupation into the proposed areas of practice? If so, what skills or training?

HF 1529 purports to be a patient safety measure. However, HF 1529 actually weakens existing law with regard to regulation of the use of lasers. Under law cited above, those authorized to use lasers would include medical doctors and osteopathic physicians, or those individuals to whom a procedure or service is delegated by a medical doctor or osteopathic physician. As such, existing law requires that all of the existing legal safeguards with regard to appropriate physician supervision for delegated medical procedures also apply to the use of lasers.

Under HF 1529, new categories of "care providers" and of "health care practitioners" are created. They are defined as follows: "Health practitioner" means a licensed practical nurse licensed under section 148.171 to 148.285, a clinical esthetician licensed under chapter 155A, a board-certified electrologist by the American Electrology Association, or a certified laser technician with a national certification."

We, of course, have no problem with nurses being considered "care providers" or "health care practitioners." However, the notion that nurses would be lumped into a category which includes a "clinical esthetician licensed under chapter 155A, a board-certified electrologist by the American Electrology Association, or a certified laser technician with a national certification," and exempts these individuals from 2013 Minnesota Statutes 147.081, Practicing Without License; Penalty is problematic. Estheticians, electrologists, and laser technicians receive no medical training and any training related to lasers is generally on their use itself (which is often provided by those selling the lasers). Additionally, the training and certification required under this proposal are not specifically related to the use of lasers on patients for medical procedures. We believe this sets a dangerous precedent.

Finally, these new definitions are unnecessary. Minnesota statutes already allow those to whom physicians delegate procedures to perform laser procedures. Existing Minnesota law already allows procedures to be delegated, both to those who are licensed and unlicensed. Under 2013 Minnesota Statutes §147.091 Grounds for Disciplinary Action, Subdivision 1. "(i) Aiding or abetting an unlicensed person in the practice of medicine, except that it is not a violation of this paragraph for a physician to employ, supervise, or delegate functions to a qualified person who may or may not be required to obtain a license or registration to provide health services if that person is practicing within the scope of that person's license or registration or delegated authority."

3. How would the public benefit by the occupation's ability to practice in the new proposed areas of practice? Is there any potential detriment to the public? Who would monitor practitioners to insure high quality service?

The public would not benefit.

The American National Standards Institute classified IIIb and IV lasers and intense pulsed light devices are considered by the Food and Drug Administration (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.

Moreover, it is important to consider that in addition to the use of medical lasers themselves, laser procedures also require the use of a medical-grade topical anesthetic. In at least two cases, the dispension of this anesthetic without appropriate supervision has resulted in patient deaths. In 2007, and again in 2009, the 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. (Food and Drug Administration. 2007, February 6. "Public Health Advisory: Life-Threatening Side Effects with the Use of Skin Products Containing Numbing Ingredients for Cosmetic Procedures." Retrieved from: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/ucm054718.htm)

4. ***Could Minnesotans effectively receive the impacted services by a means other than the proposed changes to scope of practice?***

Minnesotans are currently receiving the impacted services without an expansion of scope of practice, new definitions of "care providers," "health care practitioners," and "laser treatments." We are unaware of any evidence that access to this service is restricted or that demand exceeds the current supply.

5. ***How would the new or expanded services be compensated? What other costs and what savings would accrue and to whom? (E.g., the state, providers, patients)***

The definition of "laser treatments" contained within HF1529 is "a procedure using laser devices, intense pulsed light devices, and radio frequency devices designed to alter the aesthetic appearance of a human individual."

However, the line between something that is considered purely for aesthetic purposes and that which is considered "medically-necessary" is frequently blurred. For example, some may consider laser treatment of leg veins as being "aesthetic," and therefore largely cash procedures for which the patient is responsible for paying the full cost of the medical treatment. However, larger varicose vein treatment is primarily a medical treatment to relieve swelling, dermatitis and

ulceration, which means they may be covered by third party-payors, including Medicare Advantage and MinnesotaCare. Treatments for spider veins often connected to these varicose veins are considered aesthetic, but often require a medical procedure to address the contributory varicose veins. There are countless other examples of treatments which blur the lines between aesthetic and medically-necessary.

Existing definition of laser procedures does not delineate between those that are "medically necessary" and those that are for "altering the aesthetic appearance of a human individual." It is unclear how this new definition of laser procedures would impact patient safety protections under existing law or the consideration of these procedures as surgery under existing law.

6. ***What, if any, economic impact is foreseeable as a result of the proposed change****?*

While treatments considered by third-party payors to be "aesthetic" would be paid for by the patient, complications resulting from such procedures would be considered "medically necessary" and therefore may have an economic impact with regard to publicly-funding payors such as Medicare Advantage and MinnesotaCare.

Additionally, a recent study shows that despite only one-third of laser hair removal procedures being performed by non-physicians – including registered nurses, nurse practitioners, aestheticians or "technicians" – they accounted for about 76 percent of injury lawsuits from 2004 to 2012. That number jumped to 85.7 percent in the time period from 2008 to 2012, with 64 percent of procedures being performed outside a traditional medical setting. (Jalian, HR; et al. Increased Risk of Litigation Associated with Laser Surgery by Nonphysician Operators. *Jama Dermatol*. doi: 10.1001/jamadermatol.2013.7117. Published online October 16, 2013.)

A large number of lawsuits because of unnecessary complications due to untrained non-physicians performing medical procedures not only raises malpractice premiums, but places additional financial burdens on an already over strapped judicial system.

7. ***What other professions are likely to be impacted by the proposed changes?***

Including aestheticians, laser technicians, and electrologists in legal definitions of "healthcare practitioners" and "care providers" is a harmful precedent that marginalizes the significance of the medical training required by those professionals licensed under the Medical Practice Act, opens the door to further scope of practice expansions, and puts patients at risk.

The language contained within Section 1. [144.6586] Health Care Advertising Transparency would prohibit osteopathic physicians with legitimate, accredited specialty training from claiming board certification.

8. What position, if any, have professional associations of the impacted professions taken with respect to your proposal?

The organizations listed below are united in their opposition to HF1529 and have given their explicit permission to be listed in this document.
Minnesota Academy of Otolaryngology
Minnesota Chapter of the American College of Emergency Physicians
Minnesota Dermatological Association
Minnesota Medical Association
Minnesota Osteopathic Medical Society

American Academy of Dermatology Association
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Ophthalmology
American Academy of Otolaryngology—Head and Neck Surgery
American College of Surgeons
American Medical Association
American Osteopathic Association
American Psychiatric Association
American Society of Ophthalmic Plastic and Reconstructive Surgery
American Society of Plastic Surgeons
American Society for Dermatologic Surgery Association
American Society for Laser Medicine and Surgery

9. Please describe what efforts you have undertaken to minimize or resolve any conflict or disagreement described above.

In 2009, State Representative Maria Ruud introduced HF1860 at the bequest of Minnesota Dermatological Society. The bill was nearly 20 pages long and outlined explicitly under what circumstances and by whom FDA-designated prescription medical lasers could be used. The bill received a hearing and was tabled. No subsequent action was taken.

After several conversations with the only registered opposition to the bill, the Minnesota Association for Aesthetic Safety, the bill was significantly amended in 2011, and reintroduced as HF1225/SF707. By that time, we had compromised with the Minnesota Association for Aesthetic Safety to the extent that the bill was down to a single page.

Still, the bill did not receive consideration. Since that time, the Minnesota Dermatological Association has not pursued any new laser regulation, but instead has concentrated efforts on ensuring that existing law is enforced. The Minnesota Association for Aesthetic Safety has now gone on the opposition, hoping to weaken existing law and characterize aestheticians, electrologists, and laser technicians as "medical practitioners." Although they claim in their publicly filed form that "…they apparently seek to 'fence out' non-dermatologists and/or non-physicians from providing aesthetic laser services and do not support sensible regulation of laser services provided to Minnesota consumers." This is not the case. As you can see from our list of supporting organizations, we in no way seek to limit the scope of practice of physicians from any specialty, nor do we seek to limit the scope of practice of those health care practitioners which are currently authorized to perform these procedures under existing law, including but not limited to physicians, Physicians Assistants, and nurses. In fact, Physicians Assistants supported our 2011 bill to require a good faith medical examination by a PA, NP, or physician prior to the performance of laser medical procedures. Nurses took a neutral position on our bill at that time.

We believe this bill was written to be deliberately misleading by listing a number of oversight measures for laser procedures which already exist in current Minnesota statute, while simultaneously defining those who have no medical training—aestheticians, electrologists, and laser technicians—as "healthcare practitioners" and "care providers." HF1529 is not the patient safety measure it purports to be, but rather is a measure designed to chip away patient safety provisions which already exist in Minnesota law. As such, we urge opposition to HF1529.