A bill for an act

relating to health; regulating the use of lasers, intense pulsed light devices, and radio frequency devices; amending Minnesota Statutes 2008, section 147.081, subdivision 3; proposing coding for new law in Minnesota Statutes, chapter 147.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2008, section 147.081, subdivision 3, is amended to read:

Subd. 3. **Practice of medicine defined.** 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 unless authorized under section 147.38;

(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.

Sec. 2. **[147.38] USE OF LASERS.**

Subdivision 1. **Definitions.** (a) For the purpose of this section, the following definitions have the meanings given.

(b) "Ablative treatment" means a procedure using a laser, intense pulsed light device, or radio frequency device that is expected or intended to remove, burn, or vaporize live epithelium or its supporting structures, the dermis, or subcutaneous tissues, including fat.

(c) "Advanced medical practitioner" means a physician assistant licensed under chapter 147A or an advanced practice registered nurse licensed under sections 148.171 to 148.285.

(d) "Health practitioner" means a registered nurse or licensed practical nurse licensed under sections 148.171 to 148.285 or a clinical esthetician licensed under chapter 154.

(e) "Nonablative treatment" means a procedure using a laser, intense pulsed light device, or radio frequency device that is not expected or intended to remove, burn, or vaporize the live epidermal surface of the skin. This definition includes treatments related to laser hair removal.

(f) "Physician" means a physician or osteopath who is licensed under this chapter, is practicing within the state of Minnesota, and whose practice includes performing laser and energy-based treatments.

(g) "Supervision" means the overseeing of and accepting responsibility for the delegated nonablative treatments performed by advanced medical practitioners, health practitioners, and technicians. Supervision must only be provided by a physician as defined in paragraph (f).

(h) "Technician" means a medical technician or an electrologist.

(i) "Written protocol" means an ongoing order that is maintained on site at the facility at which the treatment is to be performed.

Subd. 2. **General restrictions on the use of lasers, intense pulsed light devices, and radio frequency devices.** (a) The use of a laser, intense pulsed light device, or radio frequency device for ablative treatments may only be performed by a physician.

(b) The use of a laser, intense pulsed light device, or radio frequency device for nonablative treatments may be performed by an advanced medical practitioner or health practitioner if the treatment has been delegated in accordance with subdivision 3; the delegating physician provides the appropriate supervision in accordance with subdivision

4; and the advanced medical practitioner or health practitioner has met the training requirements in accordance with subdivision 5.

(c) Laser-assisted hair removal may be performed by a technician if the nonablative treatment has been delegated in accordance with subdivision 3; the delegating physician provides the appropriate supervision in accordance with subdivision 4; and the technician has met the training requirements in accordance with subdivision 5.

Subd. 3. **Delegation of nonablative treatment.** (a) A physician may delegate the performance of a nonablative treatment through the use of a written protocol. The written protocol must provide, at a minimum:

(1) specific criteria to screen clients for the appropriateness of a nonablative treatment, including case selection and assessment guidelines;

(2) for clients who meet the selection criteria, the identification of the devices and settings to be used;

(3) a description of appropriate care and follow-up for common complications, injuries, or adverse reactions that may result from the nonablative treatment, including a plan to manage medical emergencies;

(4) a description of the treatment plan to be followed for each treatment procedure delegated under the written protocol, including the method to be used for documenting decisions, communicating with the delegating physician, and recording all treatment provided in the client's record;

(5) a referral process for situations when an advanced medical practitioner, health practitioner, or technician encounters an unidentifiable or suspicious-looking skin lesion or condition that may require a physician's attention; and

(6) a quality assurance plan for monitoring care provided by the advanced medical practitioner, health practitioner, or technician, including patient care review and any necessary follow-up.

(b) The delegating physician shall accept full professional responsibility for all nonablative treatment procedures performed by an advanced medical practitioner, health practitioner, or technician.

(c) Prior to delegating the performance of any nonablative treatment, the delegating physician must ensure that the advanced medical practitioner, health practitioner, or technician has satisfactorily met the training requirements described in subdivision 5. The delegating physician is responsible for ensuring that the practitioner or technician performing the treatment has demonstrated sufficient proficiency in performing a specific treatment.

(d) The written protocol must be annually reviewed by the delegating physician and the advanced medical practitioner, health practitioner, or technician and updated as necessary. The written protocol must be provided to the board or to any client upon request.

Subd. 4. **Supervision.** (a) An advanced medical practitioner may perform a delegated nonablative treatment under the general supervision of the delegating physician. For purposes of this section, general supervision does not require the on-site presence of the delegating physician so long as the physician and the advanced medical practitioner are or can be in contact with one another by telephone or other telecommunication device.

(b) A health practitioner or technician may perform any delegated nonablative treatment authorized under subdivision 2 under the indirect supervision of the delegating physician. For purposes of this section, indirect supervision requires the delegating physician be present on site at a minimum of one day per week. The health practitioner or technician must be able to contact the delegating physician by telephone or other telecommunication device.

(c) A delegating physician may provide supervision at no more than two facility locations where nonablative treatments are being performed under a written protocol.

Subd. 5. **Training requirements.** (a) Prior to the delegation of any nonablative treatment, an advanced medical practitioner, health practitioner, or technician must comply with the following training requirements:

(1) successful completion of the academic training requirements established by the Board of Medical Practice. The training must include the following subjects:

(i) fundamentals of laser operation;

(ii) bioeffects of laser radiation on the eye and skin;

(iii) significance of specular and diffuse reflections;

(iv) nonbeam hazards of lasers;

(v) nonionizing radiation hazards;

(vi) laser and laser system classifications;

(vii) control measures; and

(viii) precautions and contraindications of the use of lasers and energy-related devices in nonablative treatments; and

(2) successful completion of a clinical application training program in the use of lasers, intense pulsed light devices, or radio frequency devices, as approved by the board, that includes the actual use of each type of device that may be delegated to the advanced medical practitioner, health practitioner, or technician. The training must result in the demonstration of the ability to competently use a laser, intense pulsed light device, or

radio frequency device for nonablative treatments as determined by a course instructor or clinical trainer.

(b) Before an advanced medical practitioner, health practitioner, or technician is permitted to perform a nonablative treatment under the written protocol, the practitioner or technician must provide documentation to the delegating physician stating that the requirements of this subdivision have been met, and must demonstrate to the satisfaction of the delegating physician that the practitioner or technician is proficient in the treatment to be delegated. Documentation must include the name and address of the facility or organization at which the training took place, a description of each course or workshop taken, and a transcript or certification indicating successful completion of the required training.

(c) Practitioners and technicians performing nonablative treatments must complete a minimum of six continuing education credit hours in the use of lasers and energy-related devices each biennium. This requirement is in addition to any other continuing education requirements the practitioner is required to meet under the practitioner's license renewal process. The delegating physician must ensure that the practitioner or technician has met the continuing education requirement.

(d) The Board of Medical Practice shall establish academic and clinical training criteria as required under this subdivision. These requirements may vary based on the level of education and training required for licensure of the particular practitioner category.

Subd. 6. **Quality assurance.** Prior to delegating the performance of a nonablative treatment procedure, the physician must ensure that there is a quality assurance program at the facility at which the procedure is to be performed. The quality assurance program, at a minimum, must include the following elements:

(1) a mechanism to identify and determine the cause of complications and unintended effects of the nonablative treatments performed at the facility;

(2) a mechanism to review the adherence to the written protocol under which delegated procedures are being performed;

(3) a mechanism to monitor the quality of the nonablative treatments performed;

(4) a mechanism by which the findings of the quality assurance program are reviewed and incorporated into future written protocols and delegation orders; and

(5) ongoing training to improve the quality and performance of nonablative treatments.

Subd. 7. **Facility restrictions.** Any facility performing nonablative treatments for primarily aesthetic purposes:

(1) may not use any word in its name or in its advertising to the public that indicates or implies that the facility is a medical facility or that it provides medical services;

(2) must inform the client prior to initiating any treatment that the treatment provided by the facility is primarily for aesthetic purposes and not intended to diagnose or treat a medical condition; and

(3) must have a medical director who is licensed under this chapter.

Subd. 8. **Violation.** Any physician or osteopath who permits an advanced medical practitioner, health practitioner, technician, or any other person to perform a procedure using a laser, intense pulsed light device, or radio frequency device other than as authorized under this section shall be deemed as enabling the unlawful practice of medicine and the person performing the procedure shall be deemed in violation of section 147.081.

Sec. 3. **REVISOR'S INSTRUCTION.**

(a) The revisor of statutes shall change "sections 147.01 to 147.22" to "chapter 147" wherever it appears in Minnesota Statutes, not including chapter 147.

(b) In chapter 147, change "sections 147.01 to 147.22" to "this chapter."