193.11. **Use of Lasers.**

(a) Purpose. As the use of lasers/pulsed light devices is the practice of medicine, the purpose of this section is to provide guidelines for the use of these devices for ablative and non-ablative treatment by physicians. Nothing in these rules shall be construed to relieve the supervising physician of the professional or legal responsibility for the care and treatment of the physician's patients.

(b) Definitions. For the purpose of this section, the following definitions will apply.

(1) Advanced health practitioner--An advanced health practitioner is a physician assistant or an advanced practice nurse.

(2) Non-ablative treatment--Non-ablative treatment shall include any laser/intense pulsed light treatment that is not expected or intended to remove, burn, or vaporize the epidermal surface of the skin. This shall include treatments related to laser hair removal.

(3) On-site supervision--On-site supervision shall mean continuous supervision in which the individual is in the same building.

(4) Physician--A physician licensed by the Texas State Board of Medical Examiners.

(c) Use of lasers in the practice of medicine.

(1) The use of lasers/pulsed light devices for the purpose of treating a physical disease, disorder, deformity or injury shall constitute the practice of medicine pursuant to §151.002(a)(13) of the Medical Practice Act.

(2) The use of lasers/pulsed light devices for non-ablative procedures cannot be delegated to non-physician delegates, other than an advanced health practitioner, without the delegating/supervising physician being on-site and immediately available.

(3) The use of lasers/pulsed light devices for ablative procedures may only be performed by a physician.

(d) Delegation.

(1) If the physician provides on-site supervision, the physician may delegate the performance of non-ablative treatment through the use of written protocols to a properly trained delegate acting under adequate supervision.

(2) If the physician does not provide on-site supervision during a non-ablative treatment, the on-site supervision may be delegated to an advanced health practitioner.
(3) Prior to any non-ablative initial treatment, the physician or advanced health practitioner must examine the patient and sign the patient's chart.

(e) Supervision. Supervision by the delegating physician shall be considered adequate for purposes of this section if the physician is in compliance with this section and the physician:

(1) ensures that patients are adequately informed and have signed consent forms prior to treatment that outline reasonably foreseeable side effects and untoward complications that may result from the non-ablative treatment;

(2) is responsible for the formulation or approval of a written protocol and any patient-specific deviation from the protocol;

(3) reviews and signs, at least annually, the written protocol and any patient-specific deviations from the protocol regarding care provided to a patient under the protocol on a schedule defined in the written protocol;

(4) receives, on a schedule defined in the written protocol, a periodic status report on the patient, including any problems or complications encountered;

(5) remains on-site for non-ablative treatments performed by delegates consistent with subsection (d)(1) of this section and immediately available for consultation, assistance, and direction;

(6) personally attends to, evaluates, and treats complications that arise; and

(7) evaluates the technical skills of the delegate performing non-ablative treatment by documenting and reviewing at least quarterly the assistant’s ability:

(A) to properly operate the devices and provide safe and effective care; and

(B) to respond appropriately to complications and untoward effects of the procedures.

(f) Alternate physicians.

(1) If a delegating physician will be unavailable to supervise a delegate as required by this section, arrangements shall be made for another physician to provide that supervision.

(2) The physician providing that supervision shall affirm in writing that he or she is familiar with the protocols or standing delegation orders in use at the site and is accountable for adequately supervising care provided pursuant to those protocols or standing delegation orders.

(3) An alternate physician must have the same training in performance of non-ablative treatments as the primary supervising physician.

(g) Written protocols. Written protocols for the purpose of this section shall mean a physician's order, standing delegation order, standing medical order, or other written order that is maintained on site. A written protocol must provide at a minimum the following:

(1) a statement identifying the individual physician authorized to utilize the specified device and responsible for the delegation of the performance of the specified procedure;

(2) a statement of the activities, decision criteria, and plan the delegate shall follow when performing delegated procedures;
(3) selection criteria to screen patients for the appropriateness of non-ablative treatments;

(4) identification of devices and settings to be used for patients who meet selection criteria;

(5) methods by which the specified device is to be operated;

(6) a description of appropriate care and follow-up for common complications, serious injury, or emergencies as a result of the non-ablative treatment; and

(7) a statement of the activities, decision criteria, and plan the delegate shall follow when performing delegated procedures, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation shall be recorded within a reasonable time after each procedure, and may be performed on the patient's record or medical chart.

(h) Educational requirements for physicians and advanced health practitioners. Physicians and advanced health practitioners who are involved in the performance of non-ablative treatments must:

(1) complete basic training devoted to the principles of lasers, intense pulsed light devices and thermal, radiofrequency and other non-ablative devices, their instrumentation, physiological effects and safety requirements. For each device, the physician and advanced health practitioner must attend an initial training program. The initial training must last at least 24 hours, and include clinical applications of various wavelengths and hands-on practical sessions with each device and their appropriate surgical or therapeutic delivery systems; and

(2) maintain competence to perform non-ablative procedures and obtain at least eight hours of documented training annually regarding the appropriate standard of care in the field of non-ablative procedures.

(i) Educational requirements for delegates. A physician may delegate non-ablative procedures to a qualified delegate. The physician must ensure that the delegate complies with paragraphs (1) - (5) of this subsection prior to performing the non-ablative procedure in order to properly assess the delegate's competency.

(1) The delegate has completed and is able to document clinical and academic training in the subjects listed in subparagraphs (A) - (G) of this paragraph:

(A) fundamentals of laser operation;

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

(C) significance of specular and diffuse reflections;

(D) non-beam hazards of lasers;

(E) non-ionizing radiation hazards;

(F) laser and laser system classifications; and

(G) control measures.

(2) The delegate has read and signed the facility's policies and procedures regarding the safe use of non-ablative devices.
(3) The delegate has received or participated in at least 16 hours of documented initial training in the field of non-ablative devices.

(4) The delegate has attended at least eight hours of additional hours of documented training annually in the field of non-ablative procedures.

(5) The delegate has completed at least ten procedures of precepted training for each non-ablative procedure to assess competency.

(j) Quality assurance. The physician must ensure that there is a quality assurance program for the facility at which non-ablative procedures are performed in order for the purpose of continuously improving the selection and treatment of patients. An appropriate quality assurance program shall consist of the elements listed in paragraphs (1) - (5) of this subsection.

(1) A mechanism to identify complications and untoward effects of treatment and to determine their cause.

(2) A mechanism to review the adherence of delegates to standing delegation orders, standing medical orders and written protocols.

(3) A mechanism to monitor the quality of non-ablative treatments.

(4) A mechanism by which the findings of the quality assurance program are reviewed and incorporated into future standing delegation orders, standing medical orders, written protocols, and supervising responsibility.

(5) Ongoing training to improve the quality and performance of delegates.

(k) The deadline for compliance with the provisions of this section will be one year following the final adoption of this rule.