

RULES OF THE
ALABAMA BOARD OF MEDICAL EXAMINERS

CHAPTER 540-X-11
GUIDELINES FOR THE USE OF LASERS
AND OTHER MODALITIES AFFECTING LIVING TISSUE

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540-X-11-.01 Purpose.

(1) The use of lasers/pulsed light devices, or any energy source, chemical, or other modality that affects living tissue (when referring to the skin, anything below the stratum corneum), whether applied for surgical, therapeutic, or cosmetic purposes, is the practice of medicine.

(2) The purpose of these rules 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.

(3) These rules shall not apply to the following:

(a) Any person licensed to practice chiropractic if the laser/pulsed light device, energy source, chemical or other modality that affects living tissue is used exclusively for the practice of chiropractic;

(b) Any person licensed to practice dentistry if the laser/pulsed light device, energy source, chemical or other modality that affects living tissue is used exclusively for the practice of dentistry;

(c) Any person licensed to practice occupational therapy if the laser/pulsed light device, energy source, chemical or other modality that affects living tissue is used exclusively for the practice of occupational therapy;

(d) Any person licensed to practice optometry if the laser/pulsed light device, energy source, chemical or other modality that affects living tissue is used exclusively for the practice of optometry;

(e) Any person licensed to practice physical therapy if the laser/pulsed light device, energy source, chemical or other modality that affects living tissue is used exclusively for the practice of physical therapy.

(4) These rules shall not apply to the practice of "body art," as defined in Chapter 420-3-23 of the Administrative Rules of the Alabama Department of Public Health, which is not a part of patient treatment; and which is performed with equipment specifically manufactured for performing body art procedures and specifically used

according to the manufacturer's instructions and standard professional practice; and which is otherwise regulated by the Alabama Department of Public Health.

(5) These rules shall not apply to the use of a laser/pulsed light device, energy source, chemical or other modality that affects living tissue which occurs in "hospitals" as defined in Ala. Code §22-21-20.

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Statutory Authority: Code of Alabama §§34-24-50, 34-24-51, 34-24-53

History: Approved for publication: February 21, 2007. Approved for publication: May 16, 2007. Final Adoption: August 15, 2007. Effective Date: September 20, 2007.

540-X-11-.02 Definitions. For the purpose of these rules, the following definitions will apply:

(1) Direct Physician Supervision – Direct physician supervision shall mean that the physician is in the physical presence of the patient being treated and is directly observing the use of the modality by a delegate.

(2) Energy Source – any therapeutic source which can cause a scar or change in live tissue.

(3) Level 1 Delegate – A Level 1 Delegate is a Mid-level Practitioner who is authorized in a written job description or collaborative protocol to use a specific laser/pulsed light device or other energy source, chemical or other modality for non-ablative procedures, as designated in the written job description or collaborative

protocol and who has met the educational requirements for a Level 1 Delegate stated in these rules.

(4) Level 2 Delegate – A Level 2 Delegate is any person, other than a Level 1 Delegate, who has met the educational requirements for Level 2 Delegates stated in these rules.

(5) Mid-level Practitioner – A Mid-level Practitioner is an assistant to physician, as defined in Ala. Code §34-24-290, or an advanced practice nurse.

(6) Non-ablative Treatment – Non-ablative treatment shall include any laser/intense pulsed light treatment or other energy source, chemical or modality that is not expected or intended to remove, burn, or vaporize tissue. This shall include treatments related to laser hair removal.

(7) On-site Supervision – On-site supervision shall mean continuous supervision in which the supervising physician is in the same building as the appropriate, properly trained delegate. All treatments and procedures must be performed under the licensed physician=s direction and immediate personal supervision-*i. e.*, the physician is physically present on the premises and immediately available at all times that the non-physician is on duty, and the physician retains full responsibility to patients and the Board for the manner and results of all services rendered.

(8) Physician – A physician licensed by the Medical Licensure Commission of the State of Alabama.

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History: Approved for publication: February 21, 2007. Approved for publication: May 16, 2007. Final Adoption: August 15, 2007. Effective Date: September 20, 2007.

540-X-11-.03 Use of Lasers and Other Modalities Affecting Living Tissue in the Practice of Medicine.

(1) The use of lasers/pulsed light devices, or other energy source, chemical, or modality that affects living tissue, for the purpose of treating a physical disease, disorder, deformity or injury shall constitute the practice of medicine pursuant to Ala. Code §34-24-50.

(2) The use of lasers/pulsed light devices for **non-ablative** procedures cannot be delegated to Level 2 Delegates without the delegating/supervising physician being on-site and immediately available.

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

(4) Electrocautery may be used by a Level 1 or Level 2 delegate under direct physician supervision.

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540-X-11-.04 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) Prior to any non-ablative initial treatment, the physician must examine the patient, establish a treatment plan, and sign the patient's chart.

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History: Approved for publication: February 21, 2007. Approved for publication: May 16, 2007. Final Adoption: August 15, 2007. Effective Date: September 20, 2007.

540-X-11-.05 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, prior to treatment, have signed consent forms that outline reasonably foreseeable side effects and complications which may result from the non-ablative treatment;

(2) Is responsible for the formulation or approval of a written protocol which meets the requirements of these rules and is responsible for 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 these rules and is 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 delegate's ability to perform the following:

(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.

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History: Approved for publication: February 21, 2007. Approved for publication: May 16, 2007. Final Adoption: August 15, 2007. Effective Date: September 20, 2007.

540-X-11-.06 Written Protocols. Written protocols for the purpose of this section shall mean, 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) Documentation of 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.

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Statutory Authority: Code of Alabama §§34-24-50, 34-24-51, 34-24-53

History: Approved for publication: February 21, 2007. Approved for publication: May 16, 2007. Final Adoption: August 15, 2007. Effective

Date: September 20, 2007.

540-X-11-.07 Educational Requirements for Physicians and Level 1 Delegates.

Physicians and Level 1 Delegates who are involved in the performance of non-ablative treatments must:

(1) Complete sixteen (16) hours of 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. The basic training should include clinical applications of various wavelengths and hands-on practical sessions with devices and their appropriate surgical or therapeutic delivery systems. For each device, the physician and Level 1 Delegate must attend a training program; and

(2) Maintain competence to perform non-ablative procedures through documented training and experience regarding the appropriate standard of care in the field of non-ablative procedures and the use of specific device(s).

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Statutory Authority: Code of Alabama §§34-24-50, 34-24-51, 34-24-53

History: Approved for publication: February 21, 2007. Approved for publication: May 16, 2007. Final Adoption: August 15, 2007. Effective Date: September 20, 2007.

540-X-11-.08 Educational Requirements for Level 2 Delegates. A physician may delegate non-ablative procedures to a qualified Level 2 Delegate. For the purpose of properly assessing the Level 2 Delegate's competency, the physician must ensure that

the Level 2 Delegate complies with paragraphs (1) - (5) of this rule prior to performing the non-ablative procedure.

(1) The delegate has completed and is able to document clinical and academic training in the following subjects:

- (a) Fundamentals of laser operation;
- (b) Bio-effects 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 maintained competence to perform non-ablative procedures through documented training and experience regarding the appropriate standard of care in the field of non-ablative procedures and the use of specific device(s).

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

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History: Approved for publication: February 21, 2007. Approved for publication: May 16, 2007. Final Adoption: August 15, 2007. Effective Date: September 20, 2007.

540-X-11-.09 Remote Practice Site.

(1) For the purposes of the rules in this Chapter, a remote practice site is a practice site at which a Level 1 Delegate may, if authorized by a written job description or collaborative protocol, use lasers/pulsed light devices for non-ablative procedures without the delegating/supervising physician being on-site and immediately available.

(2) A Level 2 Delegate shall not use lasers/pulsed light devices or any energy source, chemical or other modality that affects living tissue at a remote practice site.

(3) The delegating/supervising physician shall examine the patient, establish a treatment plan, and sign the patient chart prior to a Level 1 Delegate performing the first non-ablative treatment of a patient for a particular disease or condition at a remote practice site. Subsequent non-ablative treatments which are a continuation of a treatment plan documented in the patient's chart may be performed by the Level 1 Delegate at a remote practice site without examination of the patient by the physician before each treatment.

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History: Approved for publication: February 21, 2007. Approved for publication: May 16, 2007. Final Adoption: August 15, 2007. Effective Date: September 20, 2007.

540-X-11-.10 Alternate Physicians.

(1) If a delegating physician will be unavailable to supervise a delegate as required by these rules, arrangements shall be made for an alternate physician to provide that supervision.

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

(3) Any alternate physician providing supervision shall affirm in writing to the Board of Medical Examiners that he or she is familiar with the protocols or standing delegation orders in use at the site, will be accountable for adequately supervising care provided pursuant to those protocols or standing delegation orders, and has the same training in performance of non-ablative treatments as the primary supervising physician.

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History: Approved for publication: February 21, 2007. Approved for publication: May 16, 2007. Final Adoption: August 15, 2007. Effective Date: September 20, 2007.

540-X-11-.11 Quality Assurance. The physician must ensure that there is a quality assurance program for the facility where non-ablative procedures are performed 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 section.

(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, protocols, and supervising responsibility.

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

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History: Approved for publication: February 21, 2007. Approved for publication: May 16, 2007. Final Adoption: August 15, 2007. Effective Date: September 20, 2007.

540-X-11-.12 Equipment Safety. All equipment used for the purposes stated in this Chapter must be inspected, calibrated and certified as safe to use according to the manufacturer's specifications.

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History: Approved for publication: February 21, 2007. Approved for publication: May 16, 2007. Final Adoption: August 15, 2007. Effective Date: September 20, 2007.

540-X-11-.13 Safe Use of Lasers.

In addition to the requirements of these rules, all physicians, Level 1 Delegates and Level 2 Delegates who use or operate lasers must comply with any regulations, standards, directives and guidelines for laser safety and use issued by the Occupational Safety and Health Administration, United States Department of Labor.

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Statutory Authority: Code of Alabama §§34-24-50, 34-24-51, 34-24-53
History: Approved for publication: February 21, 2007. Approved for publication: May 16, 2007. Final Adoption: August 15, 2007. Effective Date: September 20, 2007.

540-X-11-.14 Registration of Physicians Using Lasers in the Practice of Medicine.

(1) A physician who uses or offers to use a laser/pulsed light device in any facility other than a hospital, as defined in Ala. Code §22-21-20, shall register with the Alabama Board of Medical Examiners.

(2) Registration shall be accomplished on a form provided by the Board.

(3) After initially registering, it shall be the obligation of the registrant to notify the Board in writing of any change or addition of facility location where lasers/pulsed light devices are used or offered for use.

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Statutory Authority: Code of Alabama §§34-24-50, 34-24-51, 34-24-53

History: Approved for publication: February 21, 2007. Approved for publication: May 16, 2007. Final Adoption: August 15, 2007. Effective Date: September 20, 2007.

540-X-11-.15 Reporting Requirement. Reporting to the Board of Medical Examiners is required within three (3) business days of the occurrence and will include all events related to a procedure that resulted in hospitalization or third degree dermal injury.

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History: Approved for publication: February 21, 2007. Approved for publication: May 16, 2007. Final Adoption: August 15, 2007. Effective Date: September 20, 2007.

540-X-11-.16 Effective Date. The deadline for compliance with the provisions of this section will be one year following the final adoption of this rule.

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