

APA-1
Revised 4/2018

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners
Rule No. 540-X-11
Rule Title: Guidelines for the Use of Lasers and Other Modalities Affecting Living Tissue

 New X Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? NO

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? YES

Is there another, less restrictive method of regulation available that could adequately protect the public? NO

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? NO

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? NO

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

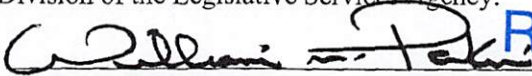
Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? NO

Does the proposed rule have an economic impact? NO

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer  **REC'D & FILED**

Date: March 20, 2023 **MAR 20 2023**

LEGISLATIVE SVC AGENCY

ALABAMA STATE BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Medical Examiners

RULE NO. & TITLE: Chapter 540-X-11, Guidelines for the Use of Lasers and Other Modalities Affecting Living Tissue

INTENDED ACTION: Amend the rules

SUBSTANCE OF PROPOSED ACTION: Amend each rule in the Chapter to update to reflect advances in technology, codify the scope of practice and training standards, and provide for the safe delegation of the use of lasers to licensed and unlicensed delegates.

Statement pursuant to Executive Order No. 735, Reducing "Red Tape":

This extensive revision to almost every rule in Chapter 540-X-11 has been in process prior to the Executive Order's adoption on March 8, 2023. Amendments were published in the November 2022 *Alabama Administrative Monthly*, and due to comments received, the Board made substantial revisions and is now publishing those revised amendments.

Additionally, the amendments are narrowly tailored to apply only to licensees who use or offer to use lasers and other modalities affecting living tissue.

Further, bringing these rules up to date is important to protect the safety of Alabama citizens, as these devices continue to evolve and have a substantial potential for harm with misuse.

TIME, PLACE, MANNER OF PRESENTING VIEWS: All interested persons may submit data, views, or arguments concerning the proposed new rule(s) and regulation(s) in writing by mail or email to: Carla H. Kruger, Office of the General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, Montgomery, Alabama 36101-0946, ckruger@albme.gov, until and including May 5, 2023. Persons wishing to submit data, views, or comments in person should contact Carla H. Kruger by telephone (334-242-4116) during the comment period. Copies of proposed rules may be obtained at the Board's website, www.albme.gov.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: May 5, 2023

CONTACT PERSON AT AGENCY: Carla H. Kruger



(Signature of officer authorized to promulgate and adopt rules or his or her deputy)

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 apply to the removal of body art with LLBD but shall not apply to the practice of placing "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.

Authors: Alabama Board of Medical Examiners ~~ad hoc Committee: Jorge A. Alsip, M.D.; Kenneth W. Aldridge, M.D.; Michael S. Clinton, M.D.; Deason C. Dunagan, M.D.; Edward C. Facundus, M.D.; Steven P. Furr, M.D.; K. Michael Hites, P.A.; Wonsuck Kim, M.D.; Elizabeth S. Martin, M.D.; Diantha Miller, CRNP; Gary D. Monheit, M.D.; Arthur F. Toole, III, M.D.; and the Alabama Board of Medical Examiners~~

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. Amended/Approved for Publication: November 17, 2022.
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540-X-11-.02 Definitions. For the purpose of these rules, the following definitions will apply:

(1) Ablative Treatment – Ablative treatment shall include any laser device, any energy-based device, any chemical, mechanical resection devices, or any modality that is expected or intended to remove, burn, or vaporize tissue extending below the dermal-epidermal junction, as well as any modality that causes coagulation necrosis or pure ablation at or below the dermal-epidermal junction.

(2) 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.

(23) Energy Source – any therapeutic source which can cause a scar or change in live tissue affect or change living tissue, including varying levels of ability to cause trauma and/or scarring.

(4) LLBD - Lasers and Light/Energy-Based Devices – 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.

(35) Level 1 Delegate – A Level 1 Delegate is a ~~Mid-level Practitioner who is~~ an assistant to physicians (PA) as defined in Ala. Code § 34-24-290, a certified registered nurse practitioner, or registered nurse (RN) 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.

(46) Level 2 Delegate – A Level 2 Delegate is ~~any person, other than a Level 1 Delegate,~~ a licensed practicing nurse (LPN) or medical assistant to include aestheticians, cosmetologists, and laser technicians authorized in a written job description or 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 protocol, and who has met the educational requirements for a Level 2

Delegate as 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, although is not expected or intended to remove, burn, or vaporize tissue, is intended to cause controlled heat-induced thermal change/injury to produce a result. This shall include treatments related to laser hair removal and other devices defined in these rules.

(7) On-site Supervision – On-site supervision shall mean continuous supervision in which the supervising physician is physically present in the same building as the appropriate, properly trained Level 1 or 2 Delegate who is using an LLBD. All treatments and procedures must be performed under the ~~licensed physician's~~ direction and immediate personal supervision ~~i. e., and~~ the physician is physically present on the premises and must be immediately available at all times that the Level 1 or 2 Delegate non-physician is on duty, and ~~the~~ The physician retains full responsibility to patients and the Board for the manner and results of all services rendered.

(8) Locally Remote Supervision – Locally remote supervision shall mean the geographic physical proximity of a delegating physician to a Level 1 Delegate who is performing a non-ablative procedure who is not providing on-site supervision but who is readily available for consultation, evaluation, referral, or direct medical intervention in person or by telemedicine. A locally remote physician's geographic physical proximity

from the patient's treatment site must not exceed the usual and customary response time of emergency management services for the locality. Locally remote supervision may only be provided by American Board of Medical Specialties or American Osteopathic Association board-certified physicians who have completed post-graduate training in lasers, light-based devices, chemical peels, and any other modality that may be used to perform ablative treatment.

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

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540-X-11-.03 Use of and Categories 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, or other condition, including cosmetic, shall constitute the practice of medicine pursuant to Ala. Code § 34-24-50.

(2) Categories of Procedures:

(a) Ablative Laser Skin Resurfacing – These procedures include the use of

fractional (partially ablative) and non-fractional (fully ablative) CO2 lasers, fractional and non-fractional Erbium-type lasers (2940nm) used deeper than 100 microns, plasma, and any other laser/device that vaporizes or removes skin beyond the dermal-epidermal junction, both fractional and non-fractional types.

(b) Non-Ablative Laser Photorejuvenation – These procedures include the use of LLBD for skin resurfacing and rejuvenation that involves targeting certain chromophores with no purposeful vaporization or removal of skin.

(c) Intense Pulsed Light (IPL) and Broad Band Light (BBL) – These procedures include the use of devices with pulsed light instead of a laser beam to target chromophores (pigment, vascularity, water). IPL devices consist of different levels with a wide range of power/energy and variable settings.

(d) Photoepilation/Laser Hair Removal, and Vascular Conditions and Lesions, and Pigmentary Conditions or Lesions.

1. Photoepilation/Laser Hair Removal procedures include the use of Ruby (694 nm), Alexandrite (755nm), Diode (800nm-810nm), ND:YAG (1064nm) lasers that target chromophore melanin, and IPL/BBL devices (when used solely for hair reduction in appropriate, fair-skinned patients).

2. Vascular Conditions and Lesions, and Pigmentary Conditions or Lesions procedures include the use of LLBDs that target a specific individual colored target and are used to treat spider veins, telangiectasias, small non-varicose vessels, rosacea, pigmented spots/lesions such as freckles, lentigines (sun/age spots), melasma, and hyperpigmentation, and benign colored lesions (Seborrheic Keratosis, Actinic Keratosis,

benign moles). LLBDs include ND:YAG, IPL, BBL, Pulsed Dye Laser, KTP, Alexandrite, radiofrequency probe procedure and LLBD categories (a) and (b) listed above.

(e) Tattoo Removal – These procedures involve the treatment of all colors of tattoos with Q-switch ND:YAG, Q-switch Ruby, Q-switch Alexandrite, or other nano/picosecond devices used specifically for tattoo removal. These procedures carry a significant risk of complications, burns, and ulcerations.

(f) Non-Laser Skin Rejuvenation – These procedures use energy sources such as radiofrequency, ultrasound, infrared, and Class III lasers that work on heat-based targeting of skin and collagen. These procedures include any ultrasonic treatments, treatments for skin tightening/fat removal (including cryolipolysis and cryotherapy), and radiofrequency micro-needling.

(g) Endovascular Radiofrequency and Laser Ablation (EVLA) – These are surgical procedures that may only be performed by physicians.

(h) Laser-Assisted Liposuction (LAL) and Power-Assisted Liposuction – These procedures involve laser or energy-assisted invasive liposuction with the use of 1064nm, 1320nm, 1440nm, 1444nm, 924/975nm, 1319nm, and ultrasounds. These procedures include VaserLipo, Smart Lipo, Cellulaze, Cool Lipo, Tickle Lipo, Accusculpt, Slim Lipo, ProLipo, CelluSmooth, BodyJet (water-assisted), and variations thereof, and may only be performed by physicians.

(i) Laser-Assisted Surgery – These procedures involve the use of lasers to assist surgeons with cutting, coagulation, tissue removal and ablation, and other surgical procedures, and may only be performed by physicians.

~~(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 and Supervision.

(1) ~~If the physician provides on-site supervision, the~~A physician may delegate the performance of non-ablative treatments as defined in these rules through the use of written protocols to a properly trained Level 1 or 2 ~~d~~Delegate acting under adequate supervision.

(2) A delegating physician shall supervise the performance of all non-ablative treatments delegated to a Level 1 or 2 Delegate. This supervision must include:

(a) Ensuring that patients are adequately informed and, prior to treatment, have signed consent forms that outline Risks, Benefits, Alternatives, and Complications.

including the disclosure of reasonably foreseeable side effects and complications that may result from the non-ablative treatment, as well as the name of the device and the procedure;

(b) Responsibility for the formulation or approval of a written protocol that meets the requirements of these rules and responsibility for any patient-specific deviation from the protocol;

(c) Substantive review and authorization, at least annually, of 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;

(d) Ensuring that any Level 1 or 2 Delegate has read and signed the facility's policies and procedures, written protocols for delegation, and these rules regarding the safe use of non-ablative devices;

(e) Prompt receipt of information from the Level 1 or 2 Delegate concerning any problem or complication encountered with any treatment;

(f) On-site or locally remote supervision for non-ablative treatments performed by Level 1 and 2 Delegates consistent with these rules, the training and experience of the delegate performing the procedure, and the risk of harm to the patient;

(g) Personal evaluation and care for complications that arise; and

(h) Evaluation of the technical skills of the Level 1 or 2 Delegate performing non-ablative treatments on an ongoing basis by formally documenting and reviewing at least annually the Level 1 or 2 Delegate's ability to perform the following:

1. To properly operate the devices and provide safe and effective care; and
2. To respond appropriately to concerns, complaints, and complications and untoward effects of the procedures.

~~(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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~~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-.065 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 be provided to the Board upon request and 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, including proof of the physician's training in accordance with these rules;

(2) A statement of the activities, decision criteria, and plan the Level 1 or 2 Ddelegate 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) Procedures for obtaining proper consent forms signed by the patient or legal guardian;

(8) Instructions for maintaining a patient's chart, which should include, at a minimum, the patient intake form, the executed informed consent, the treatment sheet and progress notes, and before and after instructions;

(79) Instructions for documentation of a patient's treatment. 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; and

(10) Instructions to contact the supervising physician immediately if complications or complaints from the patient arise.

(11) Written protocols should be signed by both the supervising physician and the corresponding Legal 1 or 2 Delegate.

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540-X-11-.076 ~~Educational~~ Initial Training Requirements for Physicians and Level 1 Delegates. Physicians and ~~Level 1 D~~delegates who are involved in the performance of non-ablative treatments must use of lasers/pulsed light devices, or any energy source, chemical, or other modality that affects living tissue, whether applied for surgical, therapeutic, or cosmetic purposes, must meet the following training requirements before utilizing a device:

(1) A physician must complete thirty (30) hours of training. A Level 1 or 2 Delegate must complete forty (40) hours of training.

(2) Appropriate training for the use of any device covered by this Chapter shall include the following topics:

(a) Theory and physics of laser and light/energy-based devices and procedures, including their effect on living tissue, tissue interaction, clinical applications.

and pre/post-treatment care;

(b) Education of skin anatomy and physiology, concerns, conditions, and diseases, including cancer, of the skin, skin type and color, chromophores, targets, general care for the skin, and recognition, management, and reporting of side effects and complications;

(c) Eight (8) hours of LLBD safety training, and

(d) Two (2) hours of training on the Board's rules and regulations, including this Chapter.

(3) Appropriate training may be obtained through residency, fellowship, private courses, Board-approved self-study, training under another cosmetic practice, training on-site with a specialty board certified physician, and company-provided or in-service training by device representatives.

(4) These initial training requirements shall not apply to any physician who holds a current registration with the Board to use pulsed light devices, or any energy source, chemical, or other modality that affects living tissue, whether applied for surgical, therapeutic, or cosmetic purposes as of January 1, 2024. Any Level 1 or 2 Delegates currently using lasers/pulsed light devices, or any energy source, chemical, or other modality that affects living tissue, whether applied for surgical, therapeutic, or cosmetic purposes under supervision of a registered physician as set forth above as of January 1, 2024, shall not be required to complete the initial training requirements in this section. Any physicians who register to use lasers/pulsed light devices, or any energy source, chemical, or other modality that affects living tissue, whether applied for

surgical, therapeutic, or cosmetic purposes after January 1, 2024, will be subject to the initial training requirements of this section. 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).

Authors: Alabama Board of Medical Examiners *ad hoc* Committee: ~~Jorge A. Alsip, M.D.; Kenneth W. Aldridge, M.D.; Michael S. Clinton, M.D.; Deason C. Dunagan, M.D.; Edward C. Facundus, M.D.; Steven P. Furr, M.D.; K. Michael Hites, P.A.; Wonsuck Kim, M.D.; Elizabeth S. Martin, M.D.; Diantha Miller, CRNP; Gary D. Monheit, M.D.; Arthur F. Toole, III, M.D.; and the Alabama Board of Medical Examiners~~

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540-X-11-.087 Educational Procedure and Device Requirements for Level-2 Physicians and Delegates. Physicians and delegates involved in the use of LLBDs must complete a minimum number of procedure/device-specific training hours, a minimum number of observed procedures, a minimum number of supervised procedures, and a minimum number of cases under supervision as set forth below.

(1) Ablative Laser Skin Resurfacing:

(a) Prior to performing procedures with any category of LLBD, physicians must complete eight (8) hours of training in the device or device category, unless the physician received training on the device in residency, in which case only four (4) hours of training are required.

(b) Level 1 and 2 Delegates shall not perform these procedures.

(2) Non-Ablative Laser Photorejuvenation:

(a) Physicians must complete eight (8) hours of training on each device unless he or she received training on the device in residency, in which case only four (4) hours of training are required.

(b) Level 1 Delegates must complete twelve (12) hours of training on each device, which includes observing the procedure performed by a trained physician and performing ten (10) cases under the direct supervision of a trained physician. After twenty (20) cases have been performed with a physician seeing a patient prior to the procedure, a Level 1 Delegate may treat a patient without a physician seeing the patient at each subsequent visit.

(c) A Level 2 Delegate must complete twenty (20) hours of training on each device, which includes observing the procedure performed by a trained physician or Level 1 Delegate, and performing fifteen (15) cases under the direct supervision of a trained physician. After twenty (20) cases have been performed with a physician seeing a patient prior to the procedure, a Level 2 Delegate may treat a patient without a physician seeing the patient at each subsequent visit.

(3) Intense Pulsed Light (IPL) and Broad Band Light (BBL):

(a) Physicians must complete eight (8) hours of training on each device, unless he or she received training in residency, in which case only four (4) hours of training are required.

(b) Level 1 Delegates must complete twelve (12) hours of training on each device, which includes observing the procedure performed by a trained physician and performing ten (10) cases under the direct supervision of a trained physician. After performing twenty-five (25) supervised cases, a Level 1 Delegate may treat patients for subsequent patient visits without direct supervision by the physician after the physician sees the patient in consult. After performing fifty (50) cases, a Level 1 Delegate may treat patients without direct supervision by the physician for the initial consult and patient consent.

(c) Level 2 Delegates must complete twenty (20) hours of training on each device, which includes observing the procedure performed by a trained physician and performing fifteen (15) cases under the direct supervision of a trained physician. After performing twenty-five (25) supervised cases, a Level 2 Delegate may treat patients for subsequent patient visits without direct supervision by the physician after the initial patient consult and consent, provided that the physician shall review the device settings for cases 26 through 50 prior to treatment. After performing fifty (50) cases, a Level 2 Delegate may treat patients for the initial treatment visit and subsequent visits without direct supervision by the physician after the physician has seen the patient in consult and consent.

(4) Photoepilation/Laser Hair Removal, Vascular Conditions and Lesions, and Pigmentary Conditions:

(a) Physicians must complete eight (8) hours of training on each device, unless he or she received training in residency, in which case only four (4) hours of training are required.

(b) Level 1 Delegates must complete twelve (12) hours of training on each device, which includes observing the procedure performed by a trained physician and performing ten (10) cases under the direct supervision of a trained physician. After performing twenty-five (25) supervised cases, a Level 1 Delegate may treat patients for subsequent patient visits without direct supervision by the physician after the physician sees the patient in consult. After performing fifty (50) cases, a Level 1 Delegate may treat patients without direct supervision by the physician for the initial consult and patient consent.

(c) Level 2 Delegates must complete twenty (20) hours of training on each device, which includes observing the procedure performed by a trained physician and performing fifteen (15) cases under the direct supervision of a trained physician. After performing twenty-five (25) supervised cases, a Level 2 Delegate may treat patients for subsequent patient visits without direct supervision by the physician after the initial patient consult and consent, provided that the physician shall review the device settings for cases 26 through 50 prior to treatment. After performing fifty (50) cases, a Level 2 Delegate may treat patients for the initial treatment visit and subsequent visits without direct supervision by the physician after the physician has seen the patient in consult

and consent.

(d) A solitary pigmented lesion shall be evaluated by a physician prior to any treatment with an LLBD device.

(5) Tattoo Removal:

(a) Physicians must complete eight (8) hours of training on each device, unless he or she received training in residency, in which case only four (4) hours of training are required.

(b) Level 1 Delegates must complete twelve (12) hours of training on each device, which includes observing the procedure performed by a trained physician and performing ten (10) cases under the direct supervision of a trained physician. After performing twenty-five (25) supervised cases, a Level 1 Delegate may treat patients for subsequent patient visits without direct supervision by the physician after the physician sees the patient in consult. After performing fifty (50) cases, a Level 1 Delegate may treat patients without direct supervision by the physician for the initial consult and patient consent.

(c) Level 2 Delegates must complete twenty (20) hours of training on each device, which includes observing the procedure performed by a trained physician and performing fifteen (15) cases under the direct supervision of a trained physician. After performing twenty-five (25) supervised cases, a Level 2 Delegate may treat patients for subsequent patient visits without direct supervision by the physician after the initial patient consult and consent, provided that the physician shall review the device settings for cases 26 through 50 prior to treatment. After performing fifty (50) cases, a Level 2

Delegate may treat patients for the initial treatment visit and subsequent visits without direct supervision by the physician after the physician has seen the patient in consult and consent.

(6) Non-Laser Skin Rejuvenation:

(a) Physicians and Level 1 and 2 Delegates must complete official certifying training by the device manufacturer or be trained by a physician certified by the manufacturer to use the device.

(b) Level 1 and 2 Delegates must complete eight (8) hours of training on each device, which includes observation of five (5) area-specific treatments by a trained physician and performing ten (10) treatments under the direct supervision of a trained physician. After completing ten (10) treatments under direct supervision, a Level 1 or 2 Delegate may complete ten (10) additional treatments without direction supervision by the physician, provided that the physician reviews the treatment plan and device settings prior to the treatment. After performing twenty-five (25) supervised cases, a Level 1 or 2 Delegate may consult, consent, and treat patients without direct supervision by the physician. Thereafter, treatments may be performed under locally remote supervision.

(7) Endovascular Radiofrequency and Laser Ablation (EVLA):

(a) Physicians must complete eight (8) hours of training on each device within a residency or fellowship program.

(b) Level 2 and 3 Delegates shall not perform these procedures.

(8) Laser-Assisted Liposuction (LAL) and Power-Assisted Liposuction:

(a) Physicians must complete eight (8) hours of training on each device within a residency or fellowship program.

(b) Level 2 and 3 Delegates shall not perform these procedures.

(9) Laser-Assisted Surgery

(a) Physicians must complete sixteen (16) hours of training on each device within a residency or fellowship program.

(b) Level 1 and 2 Delegates shall not perform these procedures.

~~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 precepted training for each non-ablative procedure to assess competency.~~

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540-X-11-.098 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~~ LLBDs for non-ablative procedures ~~without the delegating/supervising physician being on-site and immediately available~~ under locally remote supervision.

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

site.

(3) The ~~delegating/supervising~~ physician shall examine the patient, establish a treatment plan, perform informed consent of the patient, 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. If any changes are made to the treatment plan or the treatment plan ends, the physician must re-examine the patient prior to any updated treatment being performed.

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540-X-11-.409 Alternate Physicians.

(1) If a delegating physician will be unavailable to supervise a Level 1 or 2 ~~d~~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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540-X-11-.140 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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540-X-11-.121 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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540-X-11-.132 Safe Use of Lasers.

In addition to the requirements of these rules, all physicians, ~~Level 1 Delegates and Level 2 and Ddelegates~~ 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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540-X-11-.143 Registration of Physicians Using Lasers in the Practice of Medicine.

(1) AEvery physician who proposes to perform any LLBD procedure in Alabama under these rules 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 prior to performing any procedure.

(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~~ LLBD procedures occur ~~are used or are~~ offered for use.

(4) Beginning January 2024, annual registration as a provider of LLBD procedures shall be required and shall be accomplished by electronic means.

(5) Annual registration as an LLBD provider shall be due by January 31 of each year.

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540-X-11-.154 Reporting Requirement for Adverse Events. Every physician who performs or supervises the performance of a procedure covered under these rules shall report to the Board within three (3) business days the occurrence of all events related to a procedure that resulted in an emergency transfer of a patient to a hospital, unscheduled hospitalization related to the procedure, third-degree dermal injury, or death. ~~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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540-X-11-.165 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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540-X-11-.16 Continuing Education and Minimum Annual Procedures Required.

(1) Level 1 and 2 Delegates must complete a minimum number of hours of continuing LLBD education and a minimum number of procedures to continue performing LLBD procedures under these guidelines. Physicians are exempt from continued LLBD education and an annual minimum number of procedures but must maintain proper training on any procedure or device a Level 1 or 2 Delegate is allowed to utilize. If a delegate fails to meet these requirements, he or she must complete the initial training and procedure-specific training set forth in these guidelines.

(2) Level 1 Delegates must annually complete a minimum of four (4) hours of continuing LLBD education, and Level 2 Delegates must annually complete a minimum of six (6) hours of continuing LLBD education.

(3) Continuing LLBD education may include AMA PRA Category 1 CME hours, LLBD-specific medical conference hours, online study and courses, and self-study through online webinars, lectures, CME courses, and hours lectured by a physician.

(4) Continuing LLBD education obtained may be general for all LLBD procedures and not specific to every procedure performed. Continuing education should include training on LLBD theory and physics; skin anatomy and conditions/diseases; LLBD safety; treatment of conditions; recognition, management, and reporting of side

effects and complications; and overall use of LLBD procedures to treat patients.

(5) Level 1 Delegates must complete a minimum of ten (10) total LLBD procedures per year, and Level 2 Delegates must complete a minimum of thirty (30) total LLBD procedures per year.

(6) Level 1 Delegates must complete a minimum of ten (10) procedures in each procedure category they practice within, and Level 2 Delegates must complete a minimum of thirty (30) procedures in each procedure category they practice within.

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