TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

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

[ ] New [ ] 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

Date: November 18, 2022
ALABAMA STATE BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME:  Alabama Board of Medical Examiners

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

INTENDED ACTION:  Amend chapter

SUBSTANCE OF PROPOSED ACTION:  Amend rules to update categories of lasers, training requirements for practitioners, continuing education and maintenance of certification, and renewal of registration.

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 to: Carla H. Kruger, Office of the General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, Montgomery, Alabama 36101-0946, by mail or in person between the hours of 8:30 a.m. and 4:30 p.m., Monday through Friday, until and including January 4, 2023. Persons wishing to submit data, views, or comments should contact Carla H. Kruger by email (bme@albme.gov) 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:  January 4, 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

Table of Contents

540-X-11-.01 Purpose
540-X-11-.02 Definitions
540-X-11-.03 Use of and Categories of Lasers and Other Modalities Affecting Living Tissue in the Practice of Medicine
540-X-11-.04 Delegation
540-X-11-.05 Supervision
540-X-11-.06 Written Protocols
540-X-11-.07 Initial Training Requirements for Practitioners
   Educational Requirements for Physicians and Level 1 Delegates
540-X-11-.08 Procedure and Device Training Requirements for Practitioners Educational Requirements for Level 2 Delegates
540-X-11-.09 Remote Practice Site
540-X-11-.10 Alternate Physicians
540-X-11-.11 Quality Assurance
540-X-11-.12 Equipment Safety
540-X-11-.13 Safe Use of Lasers
540-X-11-.14 Registration of Physicians Using Lasers in the Practice of Medicine
540-X-11-.15 Reporting Requirement for Adverse Events
540-X-11-.16 Effective Date
540-X-11-.17 Continuing Education and Maintenance of Certification

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 Level 1 Practitioner 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.

Author: Alabama Board of Medical Examiners
History: Approved for publication: February 21, 2007. Approved for publication: May

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/pulsed
light device, any energy-based device, any chemical, or any modality that is expected or
intended to remove, burn, or vaporize tissue.

(42) 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 another practitioner.

(22) Energy Source – any therapeutic source which can 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.

(5) Level 1 Practitioner – A Level 1 Practitioner is a physician authorized in a
written job description or protocol to use a specific laser/pulsed light device or other
energy source, chemical or other modality, as designated in the written job description
or protocol, and who has met the educational requirements for a Level 1 Practitioner stated in these rules.

(6) Level 2 Practitioner – A Level 2 Practitioner is an assistant to physician (PA), as defined in Ala. Code § 34-24-290, certified registered nurse practitioner, or a certified nurse midwife 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 Practitioner stated in these rules.

(7) Level 3 Practitioner – A Level 3 Practitioner is a registered nurse (RN), 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 3 Practitioner as stated in these rules.

(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 §34-24-280, or an advanced-practice nurse.

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

(79) On-site Supervision—On-site supervision shall mean continuous
supervision in which the supervising physician Level 1 Practitioner is physically present
in the same building as the appropriate, properly trained Level 2 or 3
Practitioner/delegate who is using an LLBD. All treatments and procedures must be
performed under the licensed-physician's Level 1 Practitioner's direction and immediate
personal supervision, and the Level 1 Practitioner must be immediately available at all
times that the Level 2 or 3 Practitioner is on duty. The Level 1 Practitioner retains full
responsibility to patients and the Board for the manner and results of all services
rendered, 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.
(10) Physician – A physician licensed by the Medical Licensure Commission of the State of Alabama.

Author: Alabama Board of Medical Examiners

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, injury, or other condition, including cosmetic, shall constitute the practice of medicine pursuant to Code of Ala.-1975, 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), plasma, and any other laser/device that vaporizes or removes skin, both fractional and non-fractional types.

(b) Non-Ablative Photo-Rejuvenation – 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 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 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, 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 Laser Ablation (EVLA)** – These are surgical procedures that can only be performed by Level 1 and 2 Practitioners according to these guidelines.

(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.

(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.

(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.

Author: Alabama Board of Medical Examiners  

540-X-11-.04 Delegation.

(4) If the physician—a trained Level 1 Practitioner provides on-site supervision, the physician—said practitioner may delegate the performance of non-ablative treatments.
through the use of written protocols to a properly trained delegate Level 2 or 3 Practitioner.

Author: Alabama Board of Medical Examiners

540-X-11-.05 Supervision. Supervision by the delegating physician by a Level 1 Practitioner shall be considered adequate for purposes of this section if the practitioner physician is in compliance with this section and the Level 1 Practitioner physician:

1. Ensures that patients are adequately informed and, prior to treatment, have signed consent forms that outline Risks, Benefits, Alternatives, and Complications, which includes disclosure of reasonably foreseeable side effects and complications which may result from the non-ablative treatment, as well as the name of the device and the procedure;

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. Ensures that any Level 2 or 3 Practitioner 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;

45. Receives, on a schedule defined in the written protocol, a periodic status report on the patient, including any problems or complications encountered;
(56) Remains on-site for non-ablative treatments performed by Level 2 and 3 Practitioners delegates-consistent with these rules and is immediately available for consultation, assistance, and direction;

(67) Personally attends to, evaluates, and treats complications that arise; and

(78) Evaluates the technical skills of the Level 2 or 3 Practitioner's delegate performing non-ablative treatment on an ongoing basis by formally documenting and reviewing at least annually quarterly the Level 2 or 3 Practitioner's 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 concerns, complaints, and complications and untoward effects of the procedures.

Author: Alabama Board of Medical Examiners

540-X-11-.06 Written Protocols. Written protocols for the purpose of this section shall mean a Level 1 Practitioner's order, 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 Level 1 Practitioner/physician authorized to utilize the specified device and responsible for the delegation of the performance of the specified procedure, including proof of the Level 1 Practitioner's training in accordance with these rules;
(2) A statement of the activities, decision criteria, and plan the Level 2 or 3 Practitioner 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;

(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 & after instructions;

(9) Instructions for documentation of a patient's treatment, decisions made, and a plan for communication or feedback to the authorizing Level 1 Practitioner 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 Level 1 Practitioner immediately if complications or complaints from the patient arise.

(11) Written protocols should be signed by both the supervising Level 1 Practitioner and the corresponding Level 2 or 3 Practitioner.
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.

Author: Alabama Board of Medical Examiners

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

Delegates Initial Training Requirements for Practitioners. Practitioners involved in the 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 Level 1 Practitioner must complete sixteen (16) hours of training. A Level 2 or 3 Practitioner must complete twenty-four (24) 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 trained Level 1 Practitioner, and company-provided or in-service training by device representatives.

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).

Author: Alabama Board of Medical Examiners

540-X-11-.08 Procedure and Device Training Requirements for PractitionersEducational Requirements for Level 2 Delegates.
Practitioners involved in the use 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, Level 1 Practitioners must complete eight (8) hours of training in the device or device category, unless the Practitioner received training on the device in residency, in which case only four (4) hours of training are required.

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

(2) Non-Ablative Laser Photorejuvenation:
   (a) Level 1 Practitioners must complete eight (8) hours of training on each device.

(b) Level 2 Practitioners must complete eight (8) hours of training on each device, observe ten (10) cases performed by a trained Level 1 Practitioner, and perform ten (10) cases under the direct supervision of a trained Level 1 Practitioner. After twenty (20) cases have been performed with a Level 1 Practitioner seeing a patient prior to the procedure, a Level 2 Practitioner may treat a patient without a Level 1 Practitioner seeing the patient at each subsequent visit. A Level 1 Practitioner must always see the patient for the initial consult and patient consent.

(c) Level 3 Practitioners must have at least six (6) months of LLBD experience under a trained Level 1 Practitioner and must have performed at least fifty (50) LLBD procedures under said Level 1 Practitioner to qualify for training in this
category. After completion of these requirements, a Level 3 Practitioner must complete twenty (20) hours of training on each device, observe fifteen (15) cases performed by a trained Level 1 Practitioner, and perform fifteen (15) cases under the direct supervision of a trained Level 1 Practitioner. A trained Level 1 Practitioner must always see the patient for the initial consult and patient consent.

   (3) Intense Pulsed Light and Broad Band Light:

   (a) Level 1 Practitioners must complete ten (10) hours of training on each device.

   (b) Level 2 Practitioners must complete twelve (12) hours of training on each device, observe ten (10) cases performed by a trained Level 1 Practitioner, and perform ten (10) cases under the direct supervision of a trained Level 1 Practitioner. After performing twenty-five (25) cases, a Level 2 Practitioner may treat patients for subsequent visits without a Level 1 Practitioner seeing the patient again after the initial consult and patient consent with the Level 1 Practitioner. A trained Level 1 Practitioner must always be present for the initial consult and patient consent.

   (c) Level 3 Practitioners must have at least three (3) months of LLBD experience under a trained Level 1 Practitioner or must have performed at least fifty (50) LLBD procedures under said Level 1 Practitioner to qualify for training in this category. After completion of these requirements, a Level 3 Practitioner must complete twenty (20) hours of training on each device, observe thirty (30) cases performed by a trained Level 1 Practitioner, and perform twenty (20) cases under the direct supervision of a trained Level 1 Practitioner. A trained Level 1 Practitioner must always see the patient for the initial consult, patient consent, and initial treatment.
(4) Photoepilation/Laser Hair Removal and Vascular and Pigmentary

Conditions or Lesions:

(a) Level 1 Practitioners must complete eight (8) hours of training on each device.

(b) Level 2 Practitioners must complete sixteen (16) hours of training on each device, observe ten (10) cases performed by a trained Level 1 Practitioner, and perform ten (10) cases under the direct supervision of a trained Level 1 Practitioner. After performing twenty-five (25) supervised cases, a Level 2 Practitioner may treat patients for subsequent patient visits without direct supervision by the Level 1 Practitioner after the Level 1 Practitioner sees the patient in consult. After performing fifty (50) cases, a Level 2 Practitioner may treat patients without direct supervision by the Level 1 Practitioner for the initial consult and patient consent.

(c) Level 3 Practitioners must complete twenty (20) hours of training on each device, observe twenty (20) cases performed by a trained Level 1 Practitioner, and perform fifteen (15) cases under the direct supervision of a trained Level 1 Practitioner. After performing twenty-five (25) supervised cases, a Level 3 Practitioner may treat patients for subsequent patient visits without direct supervision by the Level 1 Practitioner after the initial patient consult and consent and the initial treatment visit with the Level 1 Practitioner. After performing fifty (50) cases, a Level 3 Practitioner may treat patients for the initial treatment visit and subsequent visits without direct supervision by the Level 1 Practitioner after the Level 1 Practitioner has seen the patient in consult and consent.

(5) Tattoo Removal:
(a) Level 1 Practitioners must complete eight (8) hours of training in the device or device category, unless the Practitioner received training on the device in residency, in which case only four (4) hours of training are required.

(b) Level 2 Practitioners must complete twenty (20) hours of training on each device, observe ten (10) cases performed by a trained Level 1 Practitioner, and perform ten (10) cases under the direct supervision of a trained Level 1 Practitioner. After performing twenty-five (25) supervised cases, a Level 2 Practitioner may treat patients for subsequent patient visits without direct supervision by the Level 1 Practitioner after the initial patient consult and consent and the initial treatment visit with the Level 1 Practitioner. After performing one hundred (100) cases, a Level 2 Practitioner may treat patients for the initial treatment visit and subsequent visits without direct supervision by the Level 1 Practitioner.

(c) Level 3 Practitioners must have at least six (6) months of LLBD experience under a trained Level 1 Practitioner and must have performed at least one hundred (100) LLBD procedures under said Level 1 Practitioner to qualify for training in this category. After completion of these requirements, a Level 3 Practitioner must complete twenty-four (24) hours of training on each device, observe thirty (30) cases performed by a trained Level 1 Practitioner, and perform twenty (20) cases under the direct supervision of a trained Level 1 Practitioner. A trained Level 1 Practitioner must always see the patient for the initial consult and patient consent.

(6) Non-Laser Skin Rejuvenation:
(a) Level 1 Practitioners must complete eight (8) hours of training on each device unless the Practitioner received training on the device in residency, in which case only four (4) hours of training are required.

(b) Level 2 Practitioners must complete eight (8) hours of training on each device, observe ten (10) cases performed by a trained Level 1 Practitioner, and perform ten (10) cases under the direct supervision of a trained Level 1 Practitioner. After performing ten (10) supervised cases, a Level 2 Practitioner may treat patients for subsequent patient visits after the initial patient consult and consent without direct supervision by the Level 1 Practitioner. After performing twenty-five (25) cases, a Level 2 Practitioner may treat patients for all visits without direct supervision by a Level 1 Practitioner.

(c) Level 3 Practitioners must complete sixteen (16) hours of training on each device, observe ten (10) cases performed by a trained Level 1 Practitioner, and perform ten (10) cases under the direct supervision of a trained Level 1 Practitioner. After performing twenty (20) supervised cases, a Level 3 Practitioner may treat patients for subsequent patient visits without direct supervision by a Level 1 Practitioner after the initial patient consult and consent with the Level 1 Practitioner and the initial treatment visit. After performing fifty (50) cases, a Level 3 Practitioner may treat patients for the initial treatment visit and subsequent visits without direct supervision by a Level 1 Practitioner after the Level 1 Practitioner has seen the patient in consult/consent.

(d) For cryotherapy only: Level 1, 2, and 3 Practitioners may complete official certifying training by a device manufacturer or be trained by a Level 1 Practitioner certified under the aforementioned condition, including observation of five (5) area-
specific treatments of a trained Level 1 Practitioner and performing five (5) treatments under the direct supervision of a trained Level 1 Practitioner. A Level 1 Practitioner must always see the patient and approve a complete treatment plan prior to the initial treatment being performed. Thereafter, treatments may be performed without Level 1 Practitioner supervision as long as the Level 1 Practitioner is readily available.

(7) Endovascular Laser Ablation (EVLA):

(a) Level 1 Practitioners must complete eight (8) hours of training on each device.

(b) Level 2 Practitioners must complete sixteen (16) hours of training on each device, observe ten (10) cases performed by a trained Level 1 Practitioner, and perform twenty (20) cases under the direct supervision of a trained Level 1 Practitioner. A Level 1 Practitioner must always see patients for the initial consult and patient consent and at each subsequent visit. Level 2 Practitioners must also be ultrasound-certified by a Board-approved organization and/or receive certification as a Registered Vascular Technician (RVT) or a Registered Phlebology Sonographer (RPhS).

(c) Level 3 Practitioners are not allowed to perform these procedures.

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

(a) Level 1 Practitioners must complete eight (8) hours of training on each device.

(b) Level 2 Practitioners must complete sixteen (16) hours of training on each device, observe ten (10) cases performed by a trained Level 1 Practitioner, and perform twenty (20) cases under the direct supervision of a trained Level 1 Practitioner. A Level
1 Practitioner must always see patients for the initial consult and patient consent and at each subsequent visit.

(c) Level 3 Practitioners are not allowed to perform these procedures.

(9) Laser-Assisted Surgery

(a) Level 1 Practitioners must complete sixteen (16) hours of training on each device.

(b) Level 2 Practitioners may be approved by the Board to perform these procedures based on the practitioner's qualifications considered on a case-by-case basis.

(c) Level 3 Practitioners 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 preceptor training for each non-ablative procedure to assess competency.

Author: Alabama Board of Medical Examiners

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 2 Practitioner-Level 1 Delegate may, if authorized by these rules and a written job description or collaborative protocol, use LLBD lasers/pulsed light-devices for non-ablative procedures without the Level 1 Practitioner delegating/supervising physician being on-site and immediately available.

(2) A Level 3 Practitioner-Level 2 Delegate shall not use LLBD lasers/pulsed light-devices or any energy source, chemical or other modality that affects living tissue at a remote practice site.

(3) The Level 1 Practitioner 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 2 Practitioner 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 2 Practitioner delegate at a remote practice site without examination of the patient by the Level 1 Practitioner physician before each treatment. If any changes are made to the treatment plan or the treatment plan ends, the Level 1 Practitioner must re-examine the patient prior to any updated treatment being performed.

Author: Alabama Board of Medical Examiners

540-X-11-.10 Alternate Physicians.

(1) If a delegating Level 1 Practitioner physician will be unavailable to supervise a Level 2 or 3 Practitioner delegate as required by these rules, arrangements shall be made for an alternate Level 1 Practitioner physician to provide that supervision.

(2) An alternate Level 1 Practitioner physician must have the same training in performance of non-ablative treatments as the primary supervising Level 1 Practitioner physician.

(3) Any alternate Level 1 Practitioner 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 the care provided pursuant to those protocols or standing delegation orders, and has the same training in the performance of non-ablative treatments as the primary supervising Level 1 Practitioner physician.
540-X-11-.11 **Quality Assurance.** The Level 1 Practitioner 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.

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.

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

In addition to the requirements of these rules, all practitioners, 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.

Author: Alabama Board of Medical Examiners

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

(1) Prior to performing any LLBD procedures as set forth in this rule, registration is required of any physician who is licensed to practice medicine in Alabama, who maintains a practice location in Alabama, who meets the definition of a Level 1 Practitioner in these rules, and who performs or offers to perform any of the LLBD procedures listed in these rules. A physician who uses or offers to use a laser/pulsed light device in any facility other than a hospital, as defined in Code of Ala. 1975, §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.
(4) Beginning January 2023, 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.

Author: Alabama Board of Medical Examiners  

540-X-11-.15 Reporting Requirement for Adverse Effects. 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.

Author: Alabama Board of Medical Examiners  

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.

Author: Alabama Board of Medical Examiners  

540-X-11-.17 Continuing Education and Minimum Annual Procedures Required.  

(1) Level 2 and 3 Practitioners 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. Level 1 Practitioners 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 2 or 3 Practitioner is
allowed to utilize. If a practitioner fails to meet these requirements, he or she must complete the initial training and procedure-specific training set forth in these guidelines.

(2) Level 2 Practitioners must complete a minimum of four (4) hours of continuing LLBD education, and Level 3 Practitioners must 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 Level 1 Practitioner.

(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 2 Practitioners must complete a minimum of ten (10) total LLBD procedures per year, and Level 3 Practitioners must complete a minimum of thirty (30) total LLBD procedures per year.

(6) Level 2 Practitioners must complete a minimum of ten (10) procedures in each procedure category they practice within, and Level 3 Practitioners must complete a minimum of thirty (30) procedures in each procedure category they practice within.

Author: Alabama Board of Medical Examiners
History: Approved for publication: