## DECLARATORY RULING OF THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS

On July 17, 2025, the Alabama State Board of Medical Examiners ("the Board") considered a request submitted by Krista Szewczyk, owner of licensed hair salon doing business as "The Mane Spa," ("Petitioner") for a declaratory ruling pursuant to Ala. Code § 41-22-11 and Ala. Admin. Code r. 540-X-1-.10, concerning the use of red light therapy sources by non-physicians under Ala. Admin. Code r. 540-X-11.

## **FACTS PRESENTED**

Petitioner presents the following factual background<sup>1</sup>:

I, [Petitioner], on behalf of the Mane Spa, a licensed salon am petitioning this Board to help define the rule as relates to [LED] light sources that are non-laser, non-pulsed and non-heated light devices. I am requesting a review of the information I have received when contacting the Board about whether or not as a salon with [LED] red light non-pulsed, non-laser, non-UV and non-heated light falls under this regulation posted. I was told that by looking at [y]our website I do fall under this regulation however when asked what nanometer doesn't fall under this regulation the corresponding individual had no answer and asked that I petition the board for an answer. I will include the information I provided to her so that we are clear on nanometer of [LED] light. I want to state that my LED lights are non-laser, non-pulsed, non-UV and non-heated. as you can see below dangerous [LED] light is the 200-425 nanometer range that allows for "tanning" it clearly burns the skin, causes damage to the skin and potentially causes cancer. It is non-regulated.

. . .

<sup>&</sup>lt;sup>1</sup> A complete copy of Petitioner's petition is attached as Attachment A.

It's important to note that many red light therapy devices emit light in the 600-1000nm range and are considered safe for various applications. Red light therapy wavelengths which lie on 600-700nm and 800-1000nm ranges of the light spectrum are by nature non-heating. We do not use heated [LED] lights. Our lights are adjustable from the 450-1000 range and we can control the strength. All of our staff are red light certified and light spectrum certified. These are non-UV ranges and what we use at the salon. If the use of lasers and other modalities applies to those of us using non-UV, non-heating and non-laser red and blue [LED] light therapy we will most likely have to close our business as it is a low-cost item to consumers and would not substantiate hiring a medical director or MD/DO to cover our spa for one service. It will also affect most gyms, salons, estheticians, cosmetologists, tanning salons and day spas.

. . .

In conclusion, I am asking the board to exclude [LED] light therapy in the range of 450-1000 nanometer that is non-laser, non-pulsed, non-UV and non-heating from the use of lasers and other modalities section of law.

## **QUESTIONS PRESENTED**

- (1) Whether a LED red light device emitting non-pulsed, non-laser, non-UV and non-heated light in the 450-1000 nanometer range is a laser under Ala. Admin. Code r. 540-X-11?
- (2) Whether a salon offering services utilizing such a device is performing non-laser skin rejuvenation under Ala. Admin. Code r. 540-X-11 such that it must be used by or under the supervision of a person licensed to practice medicine or osteopathy in Alabama?

## **ANSWER**

- (1) Any LED red light device that emits energy affecting living tissue, including skin below the stratum corneum layer, is considered an LLBD or laser and light/energy-based device under Ala. Admin. Code r. 540-X-11 if it is applied for a surgical, therapeutic, or cosmetic purpose.
- (2) Any person or business offering the utilization of devices to revise, correct, alter, or treat living tissue are subject to Administrative Rule 540-X-11, *Guidelines for the Use of Lasers and Other Modalities Affecting Living Tissue*, which requires physician supervision to perform services utilizing said devices.

## **DISCUSSION**

The Board is charged with licensing and regulating those persons engaged in the practice of medicine or osteopathy in the state of Alabama. The practice of medicine or osteopathy is defined as:

- (1) To diagnose, treat, correct, advise, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, physical or mental, real or imaginary, by any means or instrumentality;
- (2) To maintain an office or place of business for the purpose of doing acts described in subdivision (1), whether for compensation or not;

Ala. Code § 34-24-50.

Pursuant to its regulatory authority in Ala. Code § 34-24-53, the Board promulgated Administrative Rule 540-X-11, *Guidelines for the Use of Lasers and Other Modalities Affecting Living Tissue*. As stated in Ala. Admin. Code r. 540-X-11-.01, 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." Exemptions to this rule exist only for licensed chiropractors, dentists, occupational therapists, optometrists, and physical therapists acting within the scope of their respective practices.

Since the Board's rules encompass both laser and non-laser modalities, the initial question of whether a LED red light device is considered a laser under the Board's rules is irrelevant. The use of any modality that affects living tissue (when referring to the skin, anything below the stratum corneum) is considered the practice of medicine, and therefore subject to the regulation of the Board. Petitioner's device is an energy source that purports to affect living tissue. Red light devices typically penetrate human skin past the stratum corneum and into the dermis layer. When used for therapeutic or cosmetic purposes as proposed by Petitioner, these LED red light devices fall under the definition of LLBD or laser and light/energy-based devices under Ala. Admin. Code r. 540-X-11-.02(4).

The second question presented requests further examination of Ala. Admin. Code r. 540-X-11, specifically the category of procedures classified as "non-laser skin rejuvenation." Ala. Admin. Code r. 540-X-11-.03(2)(f) describes "non-laser skin rejuvenation" procedures as those procedures that "use energy sources <u>such as</u> 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" (emphasis added). The procedures listed in Ala. Admin. Code r. 540-X-11-.03(2)(f) are by no means an exhaustive list of the procedures covered under "non-laser skin rejuvenation."

All procedures that may be categorized as "non-laser skin rejuvenation" fall within the definition of the practice of medicine as it relates to the use of lasers and other modalities, meaning

that if devices are being utilized to revise, correct, alter, or treat living tissue, they will be subject to the regulation of Ala. Admin. Code r. 540-X-11. The categorization of devices and procedures allows the Board to provide specific guidance regarding the appropriate 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 for each category to ensure that these devices are being utilized safely and procedures are being performed safely.

If the Petitioner, either individually or through a business, is utilizing LED red light devices to revise, correct, alter, or treat living tissue, whether for therapeutic or cosmetic purposes, the use of such devices will be subject to Ala. Admin. Code r. 540-X-11, which requires physician supervision as well as certain training requirements prior to utilizing these devices. A key element of this analysis is Petitioner's desire to offer LED red light therapy as a service to customers. LED red light devices are available for any person to purchase and use in his or her home. A person does not need a medical license to purchase non-prescription drugs and devices and apply them to himself or herself. See Ala. Code § 34-24-55; Ala. Code § 34-24-51. However, once a person uses an LED red light device to practice medicine as defined by Alabama law, a medical license is required. Because Petitioner seeks to use an LED red light device to diagnose, treat, or correct a human disease, ailment, injury, deformity, or any other condition real or imagined, and to maintain a place of business for this purpose, Petitioner has crossed the legal boundary from permissible home use of a device into the practice of medicine. Ala. Code §§ 34-24-50 and 34-24-51.

This ruling is based upon the precise facts presented and upon statutes and rules currently in existence. Should any relevant statutes or rules be amended or repealed, this ruling may no longer be valid.

## DONE this 7th day of August, 2025.

C.M.A. "Max" Rogers, IV, M.D.

Chairman

Alabama State Board of Medical Examiners

# Attachment A to ALBME Declaratory Ruling of August 7, 2025

## PETITION FOR A DECLARATORY ORDER/CLARIFICATION

**JUNE 23, 2025** 

THE MANE SPA 6290 U S HIGHWAY 11 SPRINGVILLE, AL 35146 KRISTA SZEWCZYK

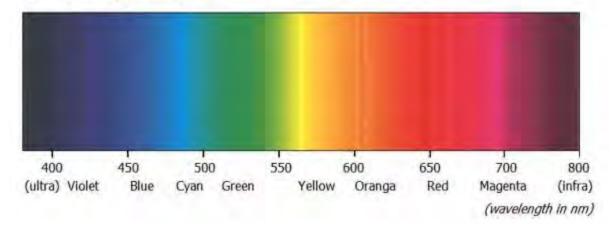
I, Krista Szewczyk on behalf of the Mane SPA, a licensed salon am petitioning this board to help define the rule AS relates to  $\underline{\textbf{LED}}$  light sources that are  $\underline{\textbf{NON-LASER}}$ ,  $\underline{\textbf{NON-PULSED}}$  and  $\underline{\textbf{NON-HEATED}}$  Light devices.

I AM REQUESTING A REVIEW OF THE INFORMATION I HAVE RECEIVED WHEN CONTACTING THE BOARD ABOUT WHETHER OR NOT AS A SALON WITH LED RED LIGHT NON-PULSED, NON-LASER, NON-UV AND NON-HEATED LIGHT FALLS UNDER THIS REGULATION POSTED. I WAS TOLD THAT BY LOOKING AT OUR WEBSITE I DO FALL UNDER THIS REGULATION HOWEVER WHEN ASKED WHAT NANOMETER DOESN'T FALL UNDER THIS REGULATION THE CORRESPONDING INDIVIDUAL HAD NO ANSWER AND ASKED THAT I PETITION THE BOARD FOR AN ANSWER. I WILL INCLUDE THE INFORMATION I PROVIDED TO HER SO THAT WE ARE CLEAR ON NANOMETER OF LED LIGHT. I WANT TO STATE THAT MY LED LIGHTS ARE NON-LASER, NON-PULSED, NON-UV AND NON-HEATED.

AS YOU CAN SEE BELOW DANGEROUS LED LIGHT IS THE 200-425 NANOMETER RANGE THAT ALLOWS FOR "TANNING" IT CLEARLY BURNS THE SKIN, CAUSES DAMAGE TO THE SKIN AND POTENTIALLY CAUSES CANCER.

IT IS NON-REGULATED.

# Visible Spectrum



It's important to note that many red light therapy devices emit light in the 600-1000 nm range and are considered safe for various applications. Red light therapy wavelengths which lie on 600-700 nm and 800-1000 nm ranges of the light SPECTRUM are by nature non-heating. We DO NOT use heated led lights. Our lights are

# ADJUSTABLE FROM THE 450-1000 RANGE AND WE CAN CONTROL THE STRENGTH. ALL OF OUR STAFF ARE RED LIGHT CERTIFIED AND LIGHT SPECTRUM CERTIFIED.

## THESE ARE NON-UV RANGES AND WHAT WE USE AT THE SALON.

IF THE USE OF LASERS AND OTHER MODALITIES APPLIES TO THOSE OF US USING NON-UV, NON-HEATING AND NON-LASER RED AND BLUE LED LIGHT THERAPY WE WILL MOST LIKELY HAVE TO CLOSE OUR BUSINESS AS IT IS A LOW-COST ITEM TO CONSUMERS AND WOULD NOT SUBSTANTIATE HIRING A MEDICAL DIRECTOR OR MD/DO TO COVER OUR SPA FOR ONE SERVICE. IT WILL ALSO AFFECT MOST GYMS, SALONS, ESTHETICIANS, COSMETOLOGISTS, TANNING SALONS AND DAY SPAS.

## GENERAL BOARD RULE

USE OF LASERS AND OTHER MODALITIES

LLBD DEFINITION BY THIS BOARD "LASERS/PULSED LIGHT DEVICES"

ABLATIVE TREATMENT – ABLATIVE TREATMENT INCLUDES ANY LLBD 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.

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 A DELEGATE'S USE OF THE MODALITY.

ENERGY SOURCE – ANY THERAPEUTIC SOURCE THAT CAN AFFECT OR CHANGE LIVING TISSUE, INCLUDING VARYING ABILITY LEVELS TO CAUSE TRAUMA AND/OR SCARRING.

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.

LEVEL 1 DELEGATE – A LEVEL 1 DELEGATE IS AN ASSISTANT TO PHYSICIANS (PA), A CERTIFIED REGISTERED NURSE PRACTITIONER, OR REGISTERED NURSE (RN) AUTHORIZED IN A WRITTEN JOB DESCRIPTION OR PROTOCOL TO USE A SPECIFIC LLBD FOR NON-ABLATIVE PROCEDURES, AS DESIGNATED IN THE WRITTEN JOB DESCRIPTION OR PROTOCOL, AND WHO HAS MET THE EDUCATIONAL REQUIREMENTS FOR A LEVEL 1 DELEGATE STATED IN BOARD RULES.

LEVEL 2 DELEGATE – A LEVEL 2 DELEGATE IS 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 LLBD 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 BOARD RULES.

NON-ABLATIVE TREATMENT – NON-ABLATIVE TREATMENT INCLUDES ANY LLBD 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 INCLUDES TREATMENTS RELATED TO LASER HAIR REMOVAL AND OTHER DEVICES DEFINED IN BOARD RULES.

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

LOCALLY REMOTE SUPERVISION — LOCALLY REMOTE SUPERVISION MEANS 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.

PHYSICIAN – A PHYSICIAN LICENSED BY THE MEDICAL LICENSURE COMMISSION OF THE STATE OF ALABAMA.

<u>IN CONCLUSION</u>, I AM ASKING THE BOARD TO EXCLUDE LED LIGHT THERAPY IN THE RANGE OF 450-1000 NANOMETER THAT IS NON-LASER, NON-PULSED, NON-UV AND NON-HEATING FROM THE USE OF LASERS AND OTHER MODALITIES SECTION OF LAW.

KRISTA SZEWCZYK, OWNER THE MANE SPA