



The Pressing Need for the Understanding and Oversight of Lasers and Light Energy Devices as Used in Today's Cosmetic and Other Medical Procedures

The American Board of Laser Surgery, Inc., 2016

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Foreward

In recent years there has been an explosion of laser and light procedures in the medical and even non-medical community, especially in the world of cosmetic procedures. Due to the number of different types of practitioners performing these procedures, and with different levels of training, or in some cases lack thereof, and the concurrent risk of injury to the patient, the American Board of Laser Surgery has developed this document to: a) explain the current state of affairs, and b) recommend what can be done to better ensure safe and effective practice of laser medicine and surgery.

We realize that readers of this document will come from different backgrounds and levels of awareness and concerns pertaining to the current state of affairs and issues at hand.

The purpose of this document is to:

- Provide information about the current issues and state of the practice of laser and light medicine and surgery, particularly in the area of cosmetic procedures.
- Recommend guidelines and regulations for training and supervision of physicians and practitioners wishing to offer these procedures so that treatments are safe and effective for patients.
- Offer assistance from the ABLs in any and all education and regulations and to help with enforcement plans.
- And above all, ensure as much as possible the safe and effective treatment of all patients.

The American Board of Laser Surgery (ABLS) seeks to bring awareness about the current state of laser and light medicine in the U.S., educate regulators, practitioners, and patients, and offer recommendations for increased training and regulations. In addition, the Board can offer assistance as necessary to those directly responsible for creating and implementing improved educational requirements for practitioners, and stronger regulations.

Dr. Warren B. Seiler III, Executive Director

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Disclaimer: Please note that the information contained in this document is the opinion of the authors and the ABLs, and the information is provided "as is" with no absolute guarantee of accuracy in all cases. We have made every effort to provide a fair and accurate assessment but also must note that changing events may impact what is written here. The Board assumes no liability whatsoever for any use of this information. It is intended as educational material only, and any specific procedures and practices that medical practitioners or clinics may use are the decision of those practitioners and clinics based on their assessment of the needs of their patients. Nothing in this document represents nor should be construed as specific medical advice. Please feel free to contact the Board should the reader have questions or concerns.

Preface

During the past 10-15 years, the number of cosmetic laser and light procedures performed on Americans has exploded. According to a 2012 report by the American Society of Plastic Surgeons, the following increases have occurred:

- IPL for various uses increased from 0 recorded procedures in 2000 to 553,293 in 2012
- Laser Hair Removal increased over 50% from 735,996 (2000) to 1,118,612 (2012)
- Laser Skin Resurfacing increased almost 200% from 170,951 (2000) to 509,055 (2012)

This increase in procedures and in potential dangers has been driven by the availability of many new laser and light technologies that can address everything from reduction of lines, wrinkles, and acne scars to the removal of unwanted hair, tattoos, age spots and skin discolorations, and many other aspects of medical skin conditions and of overall appearance. It is also driven by an increasing demand for these procedures from consumers. Younger people want to mimic the beauty they see in the media, manufacturers and service providers increasingly push youth and beauty in the multi-billion dollar cosmetic/beauty industry. In addition, many Baby Boomers are seeking to stave off the natural decline of advancing age. This latter group consists of a huge population bulge now reaching mid-50s to early 70s. This trend is projected to continue over the next decade.

Although there has been a rise in the number of medical practitioners (physicians, physician assistants, nurse practitioners, and nurses), these procedures are increasingly being provided by non-physician and even non-medical practitioners who work in an industry that is largely unregulated by the existing medical regulatory infrastructure. Today a consumer can see an ad for skin rejuvenation, that shows attractive before-after results, visit a so-called med-spa or even a well-established physician's practice, and be treated with what are highly complex pieces of laser and light equipment by non-physicians, from nurses to technicians to cosmetologists. The degree of oversight varies from adequate to virtually no supervision. Yet lasers and other light-based devices can seriously burn and maim patients when used improperly. In short, it is not as simple and always safe as the providers would have consumers believe. (Several examples of procedures gone wrong are provided in this document).

This document addresses the growing need for sensible oversight in this industry, and recommends improved training and new regulations. The American Board of Laser Surgery is uniquely qualified to do so as the sole medical specialty board providing certification that ensures physicians and non-physicians alike thoroughly understand how laser and light devices work, their complexity and potential for risk, the need for laser safety, as well as their safe and efficacious use. Founded in 1984 by 19 highly qualified physicians at the time lasers came into common use, the Board has certified hundreds of practitioners around the world.

The principal authors of this document, all officers of the Board, have nearly 60 years of combined experience in the use of all major types of laser and light devices. Together they have developed this

report for regulators in particular, and the industry as a whole, in the hope of raising awareness of both risks that need to be addressed, as well as opportunities for new regulations to promote standards of safety and efficacy for patients. Typically, internal surgical laser procedures are more regulated by state boards and hospitals. This document focuses more on the less- or “non-invasive” cosmetic laser procedures. The Board believes that the focus of regulations must be on the procedure and the person performing that procedure regardless of where the procedure is performed (hospital, physician clinic, “medspa”).

Two Examples – a Good vs. a Serious Outcome

Following are two examples of laser treatments:

- (1) a properly performed laser treatment can accomplish – 90%-plus removal of an unsightly hemangioma
- (2) severe burns (and likely lifelong scars) from a severe case of botched laser hair removal.

A “simple” treatment can have a great outcome but the same treatment can have a devastating outcome if the wrong device is used (using the wrong laser for a certain condition) or if the practitioner is not properly trained/supervised and experienced and therefore turns what should be a routine treatment into a significant complication. The burns shown in (2) are but one example of the risks of laser and light energy devices when used improperly. Preventing these types of outcomes is the principal purpose of this report.



(1) GOOD: Before-and-After photos (2 months) on removal of a posterior neck hemangioma



(2) SERIOUS: Second and third degree burns from a botched Laser/Light Hair Removal procedure

To the reader,

We realize that there will be many readers of this document and those will come from different backgrounds, positions, and awareness and concerns pertaining to the current state of affairs and issues at hand as discussed in this preface. The purpose of this document is:

- To inform you of the current issues and state of the practice of laser medicine and surgery
- To recommend guidelines and regulations for training and supervision of physicians and practitioners wishing to offer these procedures so that treatments are safe and effective for patients
- To offer assistance from the ABLS in any and all education and regulations and to help with enforcement plans
- To, above all, ensure as much as possible the safe and effective treatment of all patients

We at the ABLS would like to bring awareness to the current state of affairs, educate regulators, practitioners, and patients, and then make recommendations for training and regulations. In addition, we would like to offer any assistance necessary in education of those responsible for making laws and in helping to bring about stronger regulations. We would also help in any way to address any and all of the topics discussed in this document.

We realize that the reader may be aware of the current issues and therefore welcoming of this document and others may be less aware and not sure of the statements in this document. We ask that the reader not be overwhelmed by this document but simply look at it as a work of knowledge, information, and regulation/education suggestions to be used. The ABLS only wants to help you in a step-wise fashion to strengthen regulations for training, supervision, and treatment. We welcome the opportunity to be involved in these matters in any way you see proper.

Commitment of the ABLS

The Chief Author of this document has had discussions with his state's medical board and other state medical boards over the last few years. The issues discussed were generally regarding what laser and light/energy-based (LLBD) procedures are being performed, who is performing these procedures, what training and supervision is necessary, and what results and side effects are acceptable, and what complications are not acceptable. This author was told by a state board member that a significant roadblock to regulation of these issues was the potential lack of understanding of these procedures by state board members, regulators, and investigators. It was suggested by that state board member that what was first needed was education about these issues. This author then realized that a step back was needed to begin education of those who would regulate these practitioners and procedures. Therefore, this document is the beginning step in accomplishing that task.

The Board is committed to help educate medical practitioners through its certification process, assist medical boards with defining appropriate regulations, and facilitate the proper and safe treatment of patients with LLBD. The ABLS is available to offer its assistance to regulatory authorities. The Board believes it would be a critical improvement in the practice of LLBD procedures for the FSMB and state medical boards to require further certification for LLBD practitioners.

Outline

THE SECTIONS CONTAINED IN THIS REPORT

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1. Purpose and Scope of This Report: Discussion and Recommendations

PURPOSE: to provide...

- A thorough understanding of the critical aspects of laser and light energy devices in medicine and surgery that lead to the need for guidelines for training, and ultimately regulations for their safe and efficacious use
- The information that state medical board representatives, non-medical professionals and regulators should understand to make informed judgments on the education, testing, certification and oversight needed for medical practitioners for these devices
- Recommendations on the specific nature of the education, testing, initial certification and ongoing training and oversight necessary for the laser and light medical community
- Guidelines for the safe use of laser and light/energy-based devices by various levels of medical practitioners
- Guidelines for treatment of patients with laser and light/energy-based devices, especially in cosmetics where there has been explosive growth in the past ten years alone
- Recommendations for ensuring the ongoing safety, training, and supervision of practitioners and procedures by state medical regulatory authorities
- How the American Board of Laser Surgery can assist the state medical boards, regulatory agencies, the medical community of practitioners, and future patients

SCOPE: Due to the rapid growth of laser and light/energy-based devices in recent years and the increasing rate of complications due to under-trained and/or under-supervised practitioners, the American Board of Laser Surgery (ABLS) and its board officers have developed recommendations for the use of the procedure devices, proper safety requirements, training/supervision needs, and the consequent education, certification and regulations for use and enforcement by the Federation of State Medical Boards, individual state medical boards, and other medical specialty boards and societies. This document will discuss and make recommendations on the following:

- A useable framework to best understand the procedures that are available and what devices are used in these procedures.
- Which practitioners can and should perform each procedure category and use each device category (practitioner “levels” will be described, as well as device/procedure categories).
- The proper initial and continuing education and training necessary to properly and safely perform these procedures and use these devices. Categories of training will be described.

- The proper physician supervision of the different levels of non-physician practitioners.
- The expected, accepted, and safe outcomes of these procedures and what types of complications are unacceptable.
- Easy-to-read flow charts for medical boards and regulatory agencies to quickly determine what type of practitioner should do what type of treatment with what amount of training and supervision, and use as a basis to compare to what is currently taking place in its locale.
- The Board's recommendations for regulatory authorities on how to undertake an assessment of what is currently taking place in its locale.
- How regulatory bodies can begin the process of evaluation and action once an assessment has been completed.

2. Definition of Laser and Light/Energy-Based Devices and Procedures

A “LASER” is an acronym for Light Amplification by Stimulated Emission of Radiation. A laser device is an optical cavity, with mirrors at the ends, filled with material including crystal, glass, liquid, gas or dye. There are over 20 types of lasers in use today performing various cosmetic procedures.

A laser produces an intense beam of monochromatic light or a selected wavelength where the rays are highly focused and do not diverge, thereby producing a precise delivery of optical power to a desired target (measured in watts per area). Lasers can operate in the infrared, visible and ultraviolet regions of the optical spectrum. We will also discuss non-laser “light and other energy-based devices” and it should be understood that in the general discussions, this document will address all of these devices using the acronym “LLBD” for “Lasers and Light/energy Based Devices”. Non-laser devices use light and energy sources to treat certain targets in the skin and body including pigment, vasculature, fat reduction and other procedures. These include Intense Pulsed Light flashlamps (IPLs), high-energy LED instruments, and Radio Frequency (RF) devices. Although these are not lasers as their light is more diffuse, they all work by heating tissue in some fashion, and can still create serious outcomes when used improperly.

In order to familiarize the reader with these devices more detail is provided in Section 4. In simple terms, the majority of laser and light-energy devices utilize the action of “photothermolysis” which is heat energy interacting with living tissue targets or “chromophores” (but in far more complex ways than scalpels or other surgical instruments). Chromophores include various pigments, melanin (which creates skin color), oxygenated or deoxygenated blood vessels, and water. In simple terms, laser and light-energy devices are used for both non-ablative procedures, i.e. the heating and non-removal of tissue; and ablative procedures, i.e. the removal of tissue due to vaporization.

Lasers work at a certain wavelength, or frequency of light, measured in nanometers. Visible light ranges from 400nm to 700 nm. Lasers range from about 300 nm to 10,000 nm, depending on the type of material used to make the device. They are referred to by the type of material, such as ruby lasers, dye, alexandrite, carbon dioxide, etc. Different tissue targets, that is the chromophores mentioned above, absorb specific wavelengths better than others, thereby dictating which lasers are best for specific procedures. A laser of a particular wavelength can be made to deliver various “spot sizes”, “pulse durations” and “power densities” per area or volume of tissue that adjust the amount of light energy and resulting amount of heat to the target.

Non-laser instruments also work by delivering adjustable light energy and heat to a given area of tissue, however the light output does not consist of a single wavelength. As a result, these devices (IPLs, LEDs and RFs) are suitable for specific and generally less ablative procedures.

Laser examples: For example, CO₂ lasers are typically used for ablative resurfacing (vaporization of tissue) of the skin to reduce wrinkles and acne scars. Essentially a thin layer of dermal tissue is heated and vaporized, causing thermal contraction of the underlying skin and its collagen structure, resulting in a smoother appearance. Non-ablative lasers (i.e. non-tissue removing) in the 1400nm-2900nm frequency range can be used to heat tissue without ablation to improve texture, reduce pores, lines, wrinkles, and scars. Alexandrite (755nm) and Diode (800nm-810nm) lasers will target melanin and reduce or remove hair. Tattoos can be removed with four different wavelength lasers to target all colors. Intense Pulsed Light (IPL) can target “reds and browns” to reduce sun damage, and other pigmented abnormalities of the skin (hyperpigmentation, melasma, vascularity, rosacea and skin redness).

It is well known that doctors can cut tissue with a scalpel which has inherent dangers, and what you see is essentially what you get. Meanwhile, prospective patients who see ads for “regain your youth with GentleLase...” at a “med spa” may feel that it is not much riskier than a simple “spa” treatment or other cosmetic procedure. The problem here is that when a laser or light energy device is used improperly, the effect can be what you see (right after the procedure) is not what you ultimately get, which can be a severe burn and even permanent scarring.

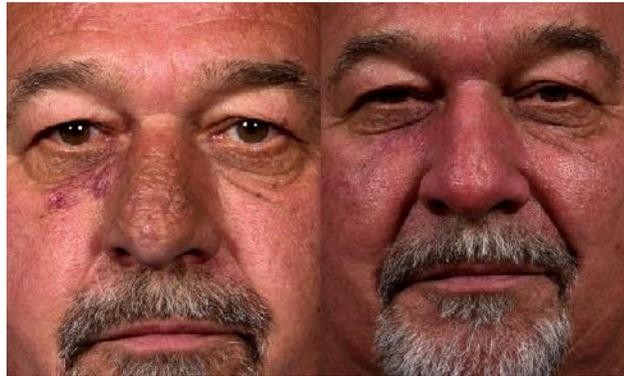
Examples of Common Lasers

Fraxel Dual 1550/1927, Lumenis Encore CO2, Lumenis One IPL & ND:YAG, Solta Clear & Brilliant 1440, etc.



When used properly, lasers and light-energy devices offer real benefits as see here:

Below: Ablative CO2 reduction of Rhinophyma, reduction in lower lid laxity, and ND:YAG removal of hemangioma



Below: Fractional CO2 reduction in sun damage, pigmentation and improvement in texture/lines



Below: IPL reduction of hyperpigmentation and sun damage



When used improperly they can seriously burn and permanently maim patients as seen here:

Second degree burn from IPL, improper settings, technique and treating a too tanned patient, leading to permanent discoloration



Poor choice of laser wavelength, parameters, technique, patient



Thermal burns and PIH after IPL



We all recognize that scalpels when improperly used can seriously cut, maim and even kill patients, and there are myriad educational and licensing requirements, regulations and boards that cover their use by doctors. Because of the complexity of laser and other light-energy devices, and the potential for misuse with serious consequences when not used properly, the ABLS advocates that the use of these devices also requires similar education, certification, oversight and regulation.

To better understand the current use of these devices in today's cosmetic industry, Sections 3 and 4 following provide an overview of the types of laser and light practitioners and procedures they typically perform.

3. Types and Levels of Practitioners

The ABLS views that there are four Levels of practitioners who perform laser and light procedures. These practitioners range from medical professionals such as MDs, DOs, Physician Assistants, Nurse Practitioners, and licensed Nurses to non-medical practitioners, many with no formal medical or laser training, such as aestheticians, cosmetologists, and “certified laser technicians” (which is commonly a misnomer and to be discussed later in more detail). Within this framework of the levels of practitioners, and the procedures they typically perform, the Board recommends regulations governing both trained medical professionals and non-medical practitioners. It is all too frequent that procedures such as laser tattoo or hair removal are performed by a technician and not a licensed medical practitioner. However, simply having some type of medical degree (MD, DO, PA, NP, RN) does not necessarily mean that degree comes with any training in laser and light principles or specialties. A common topic of debate in the medical community is about the types of physicians and other practitioners that should be allowed to perform and/or supervise these procedures, however the Board believes the more important question is be what training and education do practitioners need regardless of primary specialty. This will also be discussed later in this report.

This document expands upon a major 2009 report from the Massachusetts Medical Spa Task Force (charted under CHAPTER 81 OF THE ACTS OF 2006) in which regulations were set to govern certain procedures performed in the “medical spa” industry under a physician. However, the reader should know that the opinion of the ABLS is that the nature of the location or facility offering the procedure is much less important (hospital, clinic, “medspa”). Currently, many regulatory agencies and medical boards direct their regulations to certain types of facilities offering various procedures. For example, a state medical board may not regulate these procedures if they are offered by a medspa, and may also be more lenient in regulations if the procedures are performed in a well-established physician’s practice. If said procedure is to be offered, it should be regulated under these recommendations regardless of where it is offered. If one is to perform these medical procedures, he/she should follow a defined set of guidelines.

The specific levels the Board proposes are as follows:

1. **Level 1 Practitioner** is a Medical Physician (MD) or a Doctor of Osteopathic Medicine (DO)
 - a. PMD is the Physician Medical Director

2. **Level 2 Practitioner** is a Physician’s Assistant (PA) or a Nurse Practitioner (NP, APRN, CNP, CRNP)
 - a. Must have their state certification license to practice medicine under the rules and regulations of their individual state boards
 - b. After initial training and device specific training, these practitioners will begin performing procedures themselves with the PMD seeing the patient each visit.
 - c. After a certain number of procedures successfully performed, this practitioner may be able to treat patients in certain procedure categories without the PMD seeing the patient each time, but the PMD must see the patient in consult.

- d. After advanced level of experience, this practitioner may be able to see certain types of patients without involving the PMD in the initial consult.
3. **Level 3 Practitioner** is a Registered Nurse (RN) or Licensed Practicing Nurse (LPN)
- a. Nurses must have their state nursing license and follow their state nursing board rules and regulations.
 - b. After initial training and device specific training, these practitioners will begin performing procedures themselves with the PMD seeing the patient each visit.
 - c. After a certain number of procedures successfully performed, this practitioner may be able to treat patients in certain categories without the PMD seeing the patient each time, but the PMD must see the patient in consult. However, the Nurse must discuss the patient with the PMD and the PMD must notate/sign the patient's chart.
 - d. These practitioners will always have to have the PMD see the patient in initial consult/consent for most procedures.
4. **Level 4 Practitioner** is a non-medical practitioner such as an aesthetician, cosmetologist, or certified laser technician
- a. Level 4 practitioners will be allowed to perform certain procedures. They will always have to have a full-time PMD onsite, and with rare exception have the PMD see the patient in both initial consult/consent and every time the patient comes in for the treatment.
 - b. Aestheticians and Cosmetologists performing certain approved procedures with proper physician supervision are no longer acting as an aesthetician or cosmetologist, but rather as a laser practitioner under a physician. Therefore, they may no longer fall under the regulation of their own board, but rather the state medical board and must follow the rules and regulations of this document.
 - c. "Certified Laser Technician" is discussed in Item #13 below - often a misnomer, must be very careful with this title.
 - d. All others, such as podiatrists, chiropractors, and others may be individually certified and approved by the state medical board, but will only be able to perform a limited number of procedures under immediate and direct physician supervision. These practitioners will fall under the carefully titled "certified laser technician." This will be discussed in more detail later in this document. These practitioners should not be allowed to practice laser medicine without proper medical physician involvement under the category of Level 4 practitioner. Thus, their primary specialty gives them no advantage over any other type of Level 4 practitioner.
 - e. If Level 4 practitioners are to be utilized in a practice, the Level 1 PMD must be a full-time medical laser specialist/practitioner (laser is the sole specialty). Level 4 practitioners cannot be properly utilized in a practice in which LLBD procedures are not the full-time focus of the physician's practice and/or the physician's time is split between laser procedures and something surgical, non-cosmetic or non-laser. In this situation, the PMD must be full-time on site and see the patient for both the initial consult/consent and every time the patient is evaluated and treated by the Level 4 practitioner.

The ABLS recommends that the FSMB and State Medical Boards limit LLBD procedures to Practitioner Levels 1, 2, 3, and Level 4 Aestheticians if approved. Level 4 practitioners should be limited to performing only certain and less invasive procedures such as laser hair removal and non-laser (light-based) treatments. This will be further discussed in the sections following.

4. Procedure Categories

The following is a summary of the major categories of cosmetic laser and light procedures. These procedures are listed here with examples of the devices typical for each category. Certain categories have further subdivision due to the range and differences in devices. Section 14 will list each procedure category with details of appropriate practitioner level and level of training/supervision.

Ctrl + Click on the categories below to link to the category-specific training requirements in Section 14

1. [Ablative Skin Resurfacing](#)

- Fractional (partially ablative) and non-fractional (fully ablative) CO₂
- Fractional and non-fractional Erbium type lasers (2940nm)
- Any other laser that vaporizes or removes skin, both fractional and non-fractional types.

2. [Non-Ablative Photo-Rejuvenation](#)

- LLBD for skin resurfacing and rejuvenation that involve targeting certain chromophores
 - Generally fractionated lasers
- No purposeful vaporization or removal of skin

3. [IPL \(Intense Pulsed Light\) and BBL \(Broad Band Light\)](#)

- Device using pulsed light instead of laser beam to target chromophores
- Different levels of IPL with wide range of power/energy and variable settings

4. [Photoepilation / Laser Hair Removal](#)

- Generally Ruby (694 nm), Alexandrite (755nm), Diode (800nm - 810nm), ND:YAG (1064nm)
- Targets chromophore melanin

5. [Vascular and Pigmentary Conditions or Lesions](#)

- LLBDs that target a specific individual colored target
 - Spider Veins, telangiectasias, small non-varicose vessels, rosacea
 - Pigmented spots/lesions such as freckles, lentiginos (sun spots, age spots), melasma
 - Hyperpigmentation
 - Benign colored lesions: Seborrheic Keratosis (SK), Actinic Keratosis (AK), benign moles
- Generally treated with:
 - ND:YAG, IPL, BBL, Pulsed Dye Laser, KTP, Alexandrite, RF probe procedure, LLBD categories 1 & 2 (for advanced uses)

6. [Tattoo Removal](#)

- Treatment of all colors of tattoos
- Generally treated with:
 - Q-switch ND:YAG, Q-switch Ruby, Q-switch Alexandrite, Pulsed Dye Laser
 - Significant risk of complication, burn, and ulceration

7. Non-Laser Skin Rejuvenation

- Use of energy sources such as:
 - Radiofrequency (RF), Ultrasound (US), Infrared (IR), Class III lasers
- Generally work on heat-based targeting of skin and collagen

8. Endovascular Laser Ablation (EVLA)

- Surgical procedure, Practitioner Level 1 and 2 (according to state guidelines)

9. Laser-Assisted Liposuction (LAL) and Power-assisted Liposuction

- Laser or energy (water, US, heat) assisted invasive liposuction
- 1064nm, 1320nm, 1440nm, 1444nm, 924/975nm, 1319nm, Ultrasound
- VaserLipo, Smart Lipo, Cellulaze, Cool Lipo, Tickle Lipo, Accusculpt, Slim Lipo, ProLipo, CelluSmooth, BodyJet (water-assisted).

10. Laser-Assisted Surgery

- Generally lasers used to assist surgeons with cutting, coagulation, tissue removal and ablation, etc.
- Most common lasers are CO₂, ND:YAG, and Erbium type

Further detailed information about the recommended training for each procedure category is contained in Section 14.

5. Discussion of “non-Medical” Practitioners

This document describes different categories of medical practitioners and, in the opinion of the Board, what procedures can be safely and efficaciously performed by each level of practitioner and the level of physician supervision required. Training specific to the procedure and practitioner level is also presented. The ABLs agrees that some procedures may be performed by non-physician medical practitioners (including physician assistants, registered nurse practitioners, and nurses). However, in today’s cosmetics/beauty-provider industry, many non-medical practitioners (including podiatrists, chiropractors, aestheticians, cosmetologists, and “medical” or “laser” technicians) are performing these procedures. There is much evidence of the lack of training and physician supervision of these practitioners, depending on the state or locale.

For the sake of completeness, and later in this document, some types of practitioners will be categorized as “Level 4” practitioners per the framework in Section 3 above. Many non-medical regulatory boards (boards for aestheticians, cosmetologists, chiropractors, podiatrists, etc.) have stated that they will not regulate those persons while performing LLBD procedures. For example, the position of the Alabama Board of Cosmetology is that if one of its practitioners (i.e. aesthetician or cosmetologist) is performing a laser procedure, then he/she is no longer acting as an aesthetician and is therefore not regulated by the Board of Cosmetology (which has no experience in that procedure) for that procedure. However, the state medical board does not regulate “spas” so some facilities fall outside of either regulatory board and therefore procedures are being offered by unregulated non-medical practitioners.

The ABLs believes that once someone wants to be trained and supervised to use certain LLBD devices, as a Level 4 practitioner, they are no longer acting in their primary-trained capacity, but rather in a manner that should be regulated by the FSMB and state medical boards according to the these applicable medical regulations. This means that regardless of the primary training of non-medical practitioners such as aestheticians, cosmetologists, chiropractors, podiatrists, etc., the Board recommends they follow the guidelines for the required training, supervision and limitations of procedures as presented by the ABLs for Level 4 practitioners.

An example recommendation: a podiatrist or chiropractor cannot, under their own board and state licensing, perform LLBD procedures as this would only be the purview of a properly trained medical physician. They also cannot supervise anyone performing LLBD procedures. If they sought to perform certain procedures directly (and bearing in mind they should never be able to legally supervise others), they have to perform only any approved procedures according to the recommendations in this document. As such, they would no longer be acting in their primary specialty but rather as a Level 4 LLBD practitioner, and have to be under the direct supervision of a Level 1 physician at all times. They would have to follow the limitations delineated for Level 4 practitioners. Additional detail is provided in the discussion of the 4 practitioner levels in Section 14 following.

6. Discussion of the General State of Current LLBD Practice and Key Issues

In the 1980s and early 1990s, laser procedures were typically used in internal surgery. Since the mid-1990s, many new devices have been developed to be used in different cosmetic procedures to treat different tissues and targets. As these devices were developed, other specialties began to use them, especially in the “cosmetic” realm. Initially these cosmetic procedures were mainly performed by dermatologists and surgeons. Today these procedures are provided through many different specialties, including many “non-traditional” specialties (non-dermatology and non-surgery specialties). These procedures are now also provided by many non-physician practitioners, ranging from PAs, nurse practitioners (NPs), and nurses with formal medical training, down to aestheticians and cosmetologists who often have little or no formal training (other than for “spa” treatments) and no medical training. There are growing debates in the medical community regarding “who can or should do what”. However, it is the opinion of the ABLs that the question should not be about “which medical specialty can do what” rather...

- *how much training is necessary to properly and safely perform these procedures,*
- *which practitioners (physicians versus non-physicians) can perform which procedures, and*
- *what physician supervision over non-physicians is necessary.*

It is much more important to recognize the use and practice of these devices and procedures as a separate specialty within the “practice of medicine” and not just an “in-addition-to” procedure. It is the opinion of the ABLs that currently no primary specialty (even dermatology or plastic surgery) has proper LLBD training as part of its core curriculum (as taught in medical schools and residency/fellowship programs) and, without further specialty training afterward, LLBD training is needed to properly use these devices and treat patients safely and effectively.

Equipment manufacturers do offer limited training when devices are purchased or leased. However the author’s experience is that this is generally very cursory, and does not cover in-depth what the ABLs believes LLBD practitioners really need.

Due to the dramatic increase in use of LLBD procedures in the past 10 -15 years, some state medical boards, state nursing boards, professional societies, and other regulatory agencies have begun to put forth guidelines and recommendations (some have become state law) regarding the use of these devices and procedures on patients. However, in researching these state regulations, there is overall little specific recommendations or objective guidelines regarding which physician and non-physician practitioners can do which types of procedures, how much training is required, or what physician supervision of non-physicians is required.

The ABLs believes we must strengthen already existing guidelines, define and discuss specific issues, and assist state authorities in understanding the importance of more consistent and enforced regulations, so that, across the country, patients are treated safely and effectively. As a handful of state medical boards have already agreed, the use of LLBD procedures on patients is “the practice of medicine” and therefore should have uniform laws and regulations regarding this practice.

7. Current Issues: Complications and Problems Arising from Lack of Proper Training and Supervision

Based upon the authors' experiences, the vast majority of patients are unaware of the risks involved with cosmetic laser and light procedures. There is an imminent need for a higher level of awareness in the medical community, state medical boards, and the public in general of the potential for complications and problems pertaining to the improper training and use of these devices on patients. We are seeing some increase in patient awareness in those who have had complications. This is due to the rise in the number of places that are mistreating patients by performing procedures with misleading results, lack of informed consent for risks/benefits/alternatives, "handing off" of serious procedures to under-trained and under-supervised practitioners, and in causing complications. However, in this situation, it is likely too late. Education and awareness must increase for patients who have not yet had treatments.

Recent Survey of Physicians by the ABLS

The ABLS recently completed a survey of nearly 40 laser and light physicians. The questions asked identified the percentage of patients who had visited another facility/practice/medspa before coming to the physicians surveyed, and additionally identified what portion of those patients in turn experienced a complication of some kind. The survey also addressed patient knowledge of the risks of procedures, lack of proper consent, lack of patient satisfaction. For base data:

- Over 60% of the physicians surveyed performed both ablative and non-ablative procedures
- The physicians surveyed saw an average of 10-20 new consults per week
- Greater than 30% of these new consults on average had initially visited another practice

Of patients who had initially visited another practice:

- ***An average of 50% reported experiencing some type of complication at the previous practice***
- Only 20-40% of those visiting another practice thought before their initial visit there might be risks to these treatments
- Greater than 50% reported they were not properly informed of risks
- Greater than 50% of reported lack of expected results

Finally (and potentially most interesting) was that when the physicians surveyed were asked what type of practice those new consults had previously visited, the percentages were equal among the following types of facility:

- Another practice the surveyed physicians thought to be well-respected
- Another physician’s practice they knew or heard to have had problems
- A “medspa” they thought to be well-respected
- A “medspa” they knew or heard to have had problems

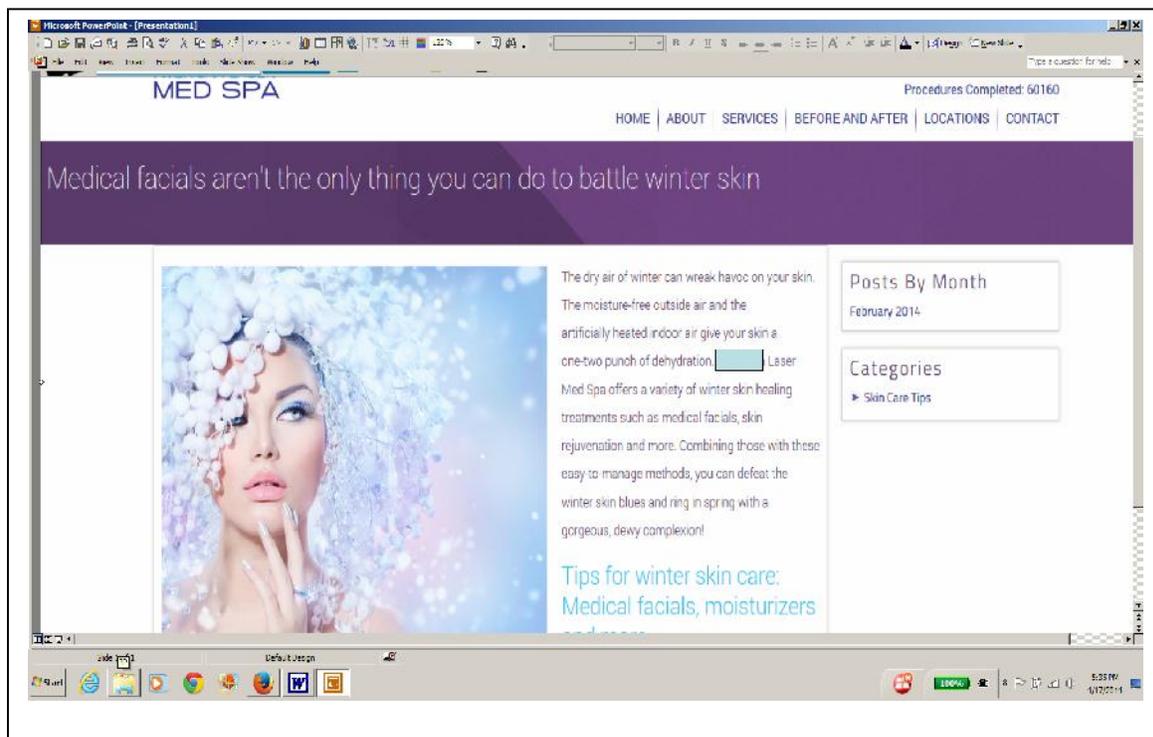
It is important to also note that of the new consults to the doctors surveyed, they reported almost just as many problems with improper consent, lack of results, and complications at the supposedly “well-respected” physicians’ practices as the ones thought to be a problem; and the same for the “well-respected” medspas as those known to be a problem. The key conclusion is that both physicians’ practices and “medspas” can be a potential major problem in the medical/cosmetic LLBD community due to improper training and supervision of its physicians and practitioners.

Role of Advertising and the Media

Advertising, television, and the media often portray these procedures as simple, effective, and safe without potential for harm. Unfortunately, prospective patients are often unaware of the potential for harm before visiting a practice that offers these procedures. Furthermore, these patients are often not made aware by the physician or practitioner of the potential for side-effects and complications; and many patients simply do not know what type of practitioner is supposed to be performing these procedures and how much a physician should be involved if the practitioner is a non-MD.

The authors anecdotally have heard too many times from patients coming to our practices, and that have gone somewhere else first, that they had a complication at this other facility and never even thought that they could be at risk (and were not told of such possible complications prior to treatment). Due to freedom of speech, websites may be free to suggest unlikely or unrealistic results as being achievable (the “one procedure that can make you look 30 years younger”) and therefore misleads prospective patients. However, some practices/facilities, through their depictions, can unrealistically and even dishonestly suggest to consumers that the risks are negligible, that anyone can get the advertised results safely, and that any practitioner can perform the procedures. In many cases there is no mention of training or qualifications for non-MDs. As a result, these practitioners and their websites can perpetuate the lack of need for awareness through the over-simplification of LLBD procedures. Sections 9 and 12 of this document provide recommendations to address these issues.

While there are hundreds of medspa websites that offer LLBD procedures, below is just one example (the name has been redacted) where on the home page youth and beauty are at the forefront, suggesting laser “skin rejuvenation” can produce the kind of results implied in the photo with possibly no more risk than a variety of non-LLBD spa treatments. When consumers see these types of pages, while they may not be technically misleading, it is not hard to understand the public’s perception can differ from reality.



Discussion of Complications

The authors, and other members of the Board, have seen an unfortunate and rising number of complications/burns from under-trained and under-supervised practitioners, even including physicians. Further discussion and examples of these complications and burns are provided in Section 8 following. Patients have reported they never knew certain procedures could hurt them and no one informed them of potential risks. This can include procedures some consider as “less invasive”, such as tattoo or hair removal (whereas facial resurfacing to reduce wrinkles is performed using more powerful lasers). Some patients we have personally seen with complications, following treatment by another practitioner, did not know that the procedure had to be performed by a physician or had to at least be supervised by a physician. Some of these patients are never even seen by a physician.

Reasons for Complications

LLBD procedures can be underestimated by both physician and non-physician practitioners. As explained at the beginning of this report, the vast majority of devices used work by the physics of photothermolysis, which imparts heat to living tissue. When performed incorrectly, mild to severe burns and even disfigurement can result.

A principal author, Dr. Seiler, has been an expert witness in a number of burn complication cases in which the patient never knew or was ever informed that the procedure could result in a burn or that a physician had to consult with the patient before the procedure was performed. In other cases, the physician or practitioner was found to not fully understand the potential for complications. It is also unfortunately all too common to see patients who have had treatments at other practices that simply provided little or no result because of the use of a “lower-end” or insufficient device, or lack of enough

knowledge and skill in using the device. This can result from a “one-laser-treats-all” approach which is simply not the case.

It is becoming more common, based on the author’s experience, and especially in smaller “med-spa”-like practices, for a LLBD device to be purchased (sometimes used, black market, etc.) and then handed off to a non-physician practitioner with little to no training of that practitioner or even the physicians themselves. In this type of location, a non-physician practitioner may also be performing procedures with no physician supervision or involvement in patient care. Although laser hair removal is probably the most common procedure/device to be improperly “handed off”, it is certainly able to cause second- and third-degree burns. LLBD hair removal is the most commonly underestimated procedure in the opinion of the authors, and the one that prospective patients usually believe is safe without any possibility of complication. Other procedures, including laser skin resurfacing, skin photorejuvenation, treatment of sun damage, pigment problems, and spider veins, also present possible of complications. With the increasing power and complexity of LLBD equipment, the need for greater awareness of potential complications and specialized training is greater than ever.

There is an increasing amount of literature discussing examples of complications and lack of practitioner training and supervision, including major news reports. Various medical and cosmetic professional societies are also concerned about these issues. The following are just two examples:

Laser Hair Removal Risks, The New York Times, Rabin, Jan. 2014:

http://well.blogs.nytimes.com/2014/01/06/laser-hair-removals-risks/?_php=true&_type=blogs&_php=true&_type=blogs&r=1

Increased Risk of Litigation Associated with Laser Surgery by Nonphysician Operators, JAMA Dermatology, Jalian et al, Apr. 2014, 150(4):407-411:

<http://archderm.jamanetwork.com/article.aspx?articleid=1754984>

In summary, these procedures can be safely used to offer patients great results if they are used by trained specialists. With the increase of the use of these devices, a set of standards for training and supervision must be established.

8. Examples of Complications from Expert Witness Work

Dr. Seiler has extensive experience as an expert witness for LLBD procedures, for both plaintiff and defense attorneys. He has found that many patients, practitioners, and figures of authority are not always aware of the possibility of complication, or severity of complication. The following are just three examples of what can and has happened:

1. **Physician's practice, laser hair removal treatment delegated to a PA:** *the patient received second and third degree burns and permanent scarring.* This case involved a physician who hired a PA from another practice. The physician allegedly assumed that the PA was properly trained and knew what she was doing from her previous experience. After research of the case, it was discovered that the PA began treating patients without proper supervision *and* without the physician himself having been properly trained. If a physician is going to delegate a procedure, he/she must master that procedure and be able to properly perform it on patients before delegating, as the physician remains responsible for the patient even if another practitioner is treating. After detailed review of depositions from the PA and physician, the patient's attorney realized the lack of sufficient training and knowledge of the physician and PA had taken place, with key aspects about the treatment proving this. Net, net the patient was improperly treated and therefore burned and permanently scarred. This case proceeded to trial seeking major damages.



2. **Laser hair removal burn by an aesthetician at a podiatrist-run medspa:** the podiatrist claimed to be a physician, and patients were unaware that the person was not an MD and treatments were provided without any physician involvement. Patient received second and third degree burns and permanent scarring as shown in the following photograph.



3. **Patient burned with an IPL device after receiving a treatment at a medspa:** a major case Dr. Seiler has consulted on involves an African American patient treated with a particular LLBD than never should have been used on her dark skin type. She was not properly consented, she was never informed that the procedure had any risks, nor was she aware or informed that her skin color should not have been effectively treated with this device. The aesthetician performing the procedure did not have enough knowledge to even properly skin type the patient (a basic knowledge requirement on an entry level to properly begin to treat a patient). Of note, she found the facility from an advertisement of the medspa and the website mentioned the presence of a physician, however no physician was involved with the facility. She was burned with the treatment and now has, over two years post treatment, obvious scarring and discoloration of her entire face.

These three examples show that there are many possible situations that can produce disastrous results. It can happen in a physician's practice who is simply not trained to perform or delegate the particular LLBD procedure, even though that doctor may be completely competent in his/her own original specialty; or in a medspa with a physician (i.e. "the medical director") who is not properly trained and involved; or a facility in which there is simply no physician.

This is testimony to the need for the recognition that LLBD procedures are medical treatments and require separate and comparative laws and regulations. Even a procedure thought to be simple like laser hair removal can cause major burns and scars and remove living tissue (hair removal procedures treat a pigmented target, can therefore burn the skin, and need to be utilized by someone with medical training in the anatomy of the skin and must not miss certain skin conditions, cancers, or disease, i.e. the need for physician involvement). For all LLBD procedures, the physician or medical practitioner must be able to diagnose the skin and its conditions, possible causes for complications, be able to properly choose an LLBD device and its settings, and recognize and manage side effects and complications.

9. Use of the Term or Any Version of “Medical,” “Medi,” “Med” in Practice/Location Name

In recent years, there has been a significant rise in the “medispa” and/or “medspa” industry which provides a wide variety of cosmetic procedures, ranging from more basic therapeutic massage through to more invasive laser procedures. Although these “spas” may be properly associated with a physician, many are utilizing LLBD procedures with little to no training or physician oversight or involvement. However, these locations often imply the involvement of a physician in the name of the location (i.e. medical, medi-, med-, use of MD in the name, etc.). The term “patients” is used throughout this document because LLBD procedures are medical procedures and are therefore offered to patients. In our view, the use of LLBD procedures on patients constitutes the actual practice of medicine, while other types of spa treatments do not. The ABLs believe that these “medspa” facilities can offer safe and efficient procedures but must follow the same medical law regarding LLBD procedures no matter what type of location or facility houses them. It is the procedure that matters, not the location.

In the past and still today, the typical spa offers traditional spa services such as massage therapy, facials, manicure/pedicures, body treatments and other skin treatments. With the rise in popularity of procedures that can more aggressively treat the skin, many facilities have started to “marry” the traditional spa services with medical services, hence the term “medspa”. In theory, this can be great for the patient who can receive both relaxing services and skin improving services. However, if the procedures discussed in this document are to be offered, they should in the Board’s opinion be done so according to the discussed recommendations.

Prospective patients are often misled by certain locations and practices to believe (or they assume) based on the advertisements, and what is either said or not said, that certain LLBD procedures are without risk, and either have no need of physician involvement (whether directed by state medical law or medical standard of care), or that the physician involved is properly trained and supervising these procedures. Websites can look both enticing and medically sound to interested patients, but the ABLs take the position that patients do not usually know what to look for or what questions to ask. For example, the authors have all seen patients who have received laser procedures at another facility, having received little or no therapeutic result or even significant skin burns. Many of these patients reported that they never knew that there were risks of complications, never signed an informed consent form, never saw a physician, and generally were lead to believe that the procedure was perfectly safe, free of risk, and results guaranteed.

It is the recommendation of the ABLs that no practice or facility should be allowed to use any form of the word “medical, medi, med” or any other word/phrase implying the presence of a physician unless there is a physician properly trained, involved and approved by the new standards and regulations recommended and set forth in this document. In addition, no facility should use LLBD procedures without said proper physician involvement, even if it is “another location” of the physician. Each location/facility should have proper on-site physician involvement. Some physicians have a medspa associated with their practice either directly attached or in a nearby location. A “second location” or a “medspa” attached to a physician’s clinic should still fall under the guidelines of the “first location”. The reader should be aware that this might lead to improper physician involvement by simple inability to be involved full-time at each location. One should not offer less regulated treatments just because the physician is busy in another clinic. There should also be information on websites, initial medical intake, and consent forms informing patients of the level of training of the practitioner, and the involvement of the physician according to state medical law. Some state medical boards already require certain levels

of physician training and involvement, but in our experience, these laws are not enforced and the public is often unaware.

Discussion of Facilities in Addition to Medspas Including Actual Physician Practices

Although the “medspa” or similar facility has become associated with the current issues, established medical practices, with physicians from many different specialties, are also not immune from issues and complications simply because an MD is present. In continuing to discuss the current issues, one must not only look at the medspas as described above but also actual established physician’s practices. It is not just some places that are “flying under the radar” and not currently falling under regulations that are the problem. The authors of this document also see across the country, physicians’ and non-physicians’ practices who are offering LLBD procedures without proper training themselves, proper training and supervision of non-physicians, and improper promotion of what these procedures are, what is their safety and risk profile, and who is really doing the procedures.

Just as one example, one of the authors has seen a patient who walked out of another well-known (or well-established) physician’s office because she heard the physician tell a “tech” in the office that she didn’t have time to do a spider vein treatment and that the tech needed to do it. This patient overheard the tech saying that she had never used the laser before, but the physician told her the settings and when she walked into the treatment room, this patient left. Patients often assume that an established medical practice must be operating legally and with well-trained physicians and practitioners when offering these procedures. The members of the ABLs have seen just as many problems with established medical practices (that are not promoted as medspas) due to lack of training, knowledge and supervision of the responsible physician, and quick and inappropriate delegation of procedures to under-trained and improperly supervised non-physician practitioners.

In summary, the ABLs believe that no use of the word “medical” or any form of “med” should be used by a facility without a licensed physician medical director in good standing who is directly responsible for the care and treatment of patients. This should include “additional locations” of physician practices. Otherwise the Board recommends that the facility/practitioner should be subject to state and federal laws regarding misrepresentation of a physician and the practice of medicine without a license. We believe non-physicians performing LLBD procedures need an effective level of proper physician supervision according to the recommendations in this document. (I think since we are directing this to state authorities we might want to avoid “federal”?) one of the authors has been a consultant for the DEA on these issues and has found that federal laws outside of state medical laws regarding the practice of medicine without a license will help strengthen the enforcement of these recommendations.) The recommendations in this document should apply to the devices and procedures offered, regardless of the type of practice or facility offering them.

Based on the above, this document describes in Section 14 the levels of practitioners, training, and supervision for LLBD procedures *as a separate medical specialty*, regardless of the location, practitioner, or primary medical specialty of the physician’s practice.

10. Discussion of Primary Specialty Versus Obtained Specialty Training

In the opinion of the Board, the practice and use of laser and light/energy-based treatments requires the acquisition of specialized training and knowledge to offer safe and effective treatments to patients. This is true and standard for any specialty in medicine and surgery. One must recognize the use and practice of these devices and procedures as a separate medical specialty, and not just an “in addition to” procedure that anyone can utilize with little to no additional training beyond the primary specialty training. It is the opinion of the ABLS that no primary medical or surgical specialty has the proper training as part of its core (medical school, residencies, fellowships...) , without further “after-market” specialty training, to properly use these devices and treat patients with these procedures. For example, there are a number of ABLS Diplomates who came from traditional scalpel-based surgical gynecology and migrated into use of surgical lasers and /or cosmetic procedures. These physicians had the opportunity to learn the biophysics of LLBD devices and how different these are from other surgical instruments.

LLBD procedures must be respected as its own medical specialty due to the complex nature of how these devices work on living tissue. A specialty akin to this is radiology, where the complexity of the equipment and potential for harm has necessitated regulation and specialized training requirements that are based on the equipment, and not simply the medical specialty for which radiological devices are used (which of course are numerous).

With the rise in popularity of these laser and light procedures, some specialties such as dermatology and surgery (mostly plastic/cosmetic) have started to incorporate into their core curriculum, during residency and fellowship, the basic training in some of these procedures. The level of training is usually dependent on the individual program. Further education, training, and practice is usually necessary to properly specialize in the practice of LLBD procedures. It is commonly thought that a one-day training session by a sales representative for a device company, after a device is purchased, is sufficient to master the knowledge and technique required to treat patients with said device. It is hard to believe that this has become accepted by many physicians and practitioners as the proper amount of training before firing a laser on a patient. A full understanding and appreciation of the complex biophysics by which lasers operate cannot be learned in a day.

As a result, this document will provide in Section 14 recommendations by medical specialty for the safe and efficacious use of laser and light/energy-based devices and procedures.

11. Description of the practice of LLBD procedures as a separate specialty with the need for its own individual set of regulations, laws, certifications, training requirements, supervision, and treatment/safety protocols

As discussed in the previous section, although some of these devices and procedures have been available for years, the use and practice of LLBD procedures has become its own medical specialty due to new equipment, the complexity of these devices, and the ever-growing use of these devices/procedures by many different types of practitioners. Therefore, since this is a medical specialty based upon procedures, it is the procedures that should be regulated.

State medical boards, regulatory agencies, and the general medical community should establish laws, certifications, training requirements, supervision regulations, and treatment protocols to ensure the safe and effective treatment of patients.

The ABLS is the only LLBD-specific certifying medical specialty board today in the world, with Diplomates in the US as well as many different countries. The ABLS is able to offer assistance to the Federation of State Medical Boards, individual state medical boards, and other regulatory agencies for these needs. Specifics will be discussed regarding the proper levels of practitioners for different procedures, the training necessary for each level and by device/procedure to properly and safely treat patients, and the requirements for physician supervision of non-physician practitioners for certain procedures that may be delegated.

Laparoscopy is a growing medical specialty and has already begun to establish itself as a separate specialty with a fellowship and specialized training. Some surgeons perform laparoscopic procedures as the majority procedure in their practice. The specialty of laser procedures is similar in that physicians have established medical practices entirely devoted to laser procedures. Therefore, similar specialty training and regulation is not only becoming more popular but should also become solid accepted principles.

Typically, internal surgical laser procedures are more regulated by state boards and hospitals, so this document focuses more on the less or non-invasive (and more cosmetic) laser procedures. The focus of regulations should be on the procedure and the person performing that procedure regardless of where the procedure is performed (hospital, physician clinic, "medspa").

12. Recommendations for Regulation of Practice Titles, Websites, Advertising, and Patient Forms/Consent Disclosure of Rules

The reader should understand patient perception in order to understand why the ABLS makes the recommendations in this section. The next paragraph describes a typical patient's perception that may lead to lack of concern and caution when undergoing a laser or light procedure. This section will then explain the recommendations of the ABLS for oversight of websites, advertising, and both verbal and written consent for procedures.

WHAT DRIVES COMMON PATIENT PERCEPTIONS

The authors of this document agree that the common perception of a novice patient, one who knows little about laser or light treatments, is that these LLBD procedures are safe, for the most part harmless, and always effective. This holds even truer for the more common and "simple" (as perceived) procedures like laser hair removal. In our opinion, this misconception is typically caused by a number of factors:

1. The media and general advertisements often are positioned to lead prospective patients to believe that anyone can have these procedures done, that they are perfectly safe, and that they are always effective.
2. Websites typically make no mention of the need for physician involvement, supervision and training of the practitioner.
3. Physicians and practitioners may not fully inform the patient of the true risks of laser and light procedures. This can include both verbally during a full consult, and in writing. *Practitioners also may not check that an understanding of the consent form exists before patients simply sign it.* In addition, over-simplified simple consent forms may be used and these can lead one to believe that the risks are negligible.
4. Practitioners may disguise the seriousness of these procedures by offering them in a beautiful, relaxing environment that also may make a patient let his or her level of concern diminish because they feel safe at such a nice place. Just because the practice facility looks nice, does not mean it offers proper care.
5. Patients are made to feel like if they are getting an easy "common" procedure done, and that everything should be fine.

The authors have heard too many times from patients, who have been somewhere else, that they never thought the procedure could hurt them or leave them with little or no satisfactory results, that they did not think a physician had to be involved in any way, and that "the place just seemed so nice" that it made them feel even less concerned. However, if you were to be in a neurosurgeon's office, which traditionally looks medical, and were told that you had to have surgery, your initial response would be one of serious concern. That is how most other medical practices and specialties are perceived: as serious medicine.

The ABLS's main purpose in this section is to help change the perception of LLBB procedures as non-medical, and to make patients aware of the truly serious medical nature of these procedures, which require the proper medical training to perform them as any other medical specialty.

Patients' perceptions can be changed if proper consult and verbal/written consent is provided by a properly trained professional. Because these are mainly elective procedures in cosmetics, and the medspa moniker is often used, even more honest presentation may still imply this is not much different than going to a beauty salon and getting a facial, while everyone knows internal procedures in surgery are more "heavy duty" and patients typically consider the risks and ask more questions. In summary, although a "spa" type atmosphere or a "beautiful cosmetic practice" versus a traditional physician's office may make a patient less concerned with a procedure, if the patient receives the proper consultation and consent, it will not matter what the patient thought prior to entering the facility. It is the job of the physician to educate the patient regardless of the treatment proposed and regardless of the patient's prior knowledge of the treatment. However, the regulations and discussions in this document should also help to educate the patient in general before they even enter a facility, to know what is proper and what is not.

EXAMPLE OF DR. SEILER'S PRESENTATION & PROCEDURES

To educate the reader about websites, we will offer up Dr. Seiler's website, www.seilerskin.com. Although it does contain marketing and advertising that are consumer friendly, patients and practitioners who have spent time reading the provided material often state that it is clear to them from the information that the practice is one that solely specializes in cosmetic laser and light procedures and aesthetic injections. From all of the information about Dr. Seiler, his own experience, his professional training and board examining of others, the information about the procedures, patient forms such as consents and pre/post instructions, real pictures of patients, patient and physician reviews and testimonials, and extra information through the blogs to educate patients and practitioners, the information makes it clear that his practice is a highly trained specialty laser center.

ABLS RECOMMENDATIONS FOR PATIENT INFORMATION AND EDUCATION

The position of the ABLS is not that websites and advertising should not be able to promote services in a consumer-oriented manner. However, patients should be able to see that the physician and his/her staff have the proper training and any preconceived notion of simplicity of these procedures would be addressed. Each state medical board could make certain requirements of simply listing state laws regarding the practice of these procedures. Then, no matter how "pretty" the website is, the patient will be better informed of the true medical nature of these procedures.

The ABLS believes that when overall guidelines are strengthened, ***this should be available to the patient through the medical board's website and even on each practice's website*** (a type of "seal of approval"). This could provide state medical boards with a way to strengthen patient education and awareness of the need for procedures to be properly offered. We are not suggesting that authorities strictly regulate websites and advertising per se, but provide for ease of access to information that patients need to be better educated in their decisions for LLBD treatments.

ABLS RECOMMENDATIONS FOR TRAINING AND MEDICAL SUPERVISION:

Regardless of whether LLBD procedures are offered by a full-time laser specialist physician (entire practice devoted to the practice of laser medicine and surgery) or as a part-time ("in addition to" the primary practice), the same laws of practitioner level, training, and physician supervision should apply. Furthermore, the same laws and regulations should apply for each location or "additional practice location" under the physician. Additional locations must follow the same laws regarding proper

physician physical presence and supervision (which may require another properly trained physician at the “other” location for proper physician involvement).

In addition to the recommendations in Section 9 for proper naming of the practice and location, the ABLs recommends that all practice websites, practice information, and patient forms include the following, in addition to verbally discussing the following with each incoming patient:

1. Every type of practice which offers LLBD procedures must have a trained Level 1 physician practitioner as the medical director and supervisor of the practice. This is regardless of the primary specialty or the practice time involved in offering these procedures.
2. This Level 1 Physician Medical Director (PMD) should be listed on the practice literature, website, medical intake/history, and consent forms as the physician directly responsible for the care of patients.
3. Patients should be properly informed of which procedures require which level of practitioner.
4. Patients should be properly informed of how much physician supervision of non-physician practitioners (Levels 2-4) is legally required.
5. For Practitioner Levels 2-4, and for certain procedure categories, as is described in the following sections, the physician must be involved in the initial consult with the patient. Exceptions to this will be recommended only for Physician Assistants and Certified Nurse Practitioners performing certain procedures and who are licensed according to state medical law to offer medical treatments to patients without initial physician physical supervision (treatment “lateral” to a physician) once certain criteria have been met. More will be discussed regarding which procedures can be offered according to this exception.
6. Proper consulting with and consenting of the patient is required before offering the procedure. This should include both verbal and written consent discussing risks, benefits, alternatives, complications, and disclosures.
7. Protocols for use of each LLBD, treatment, consent, and safety should be in writing and available for patient inspection upon request.
8. Laws and regulations apply for each practice location. “On-site” laws apply to each location.
9. As with any other medical/surgical specialty, the physician, practitioners, practice and use of LLBD procedures must be registered with the individual state medical board.

13. Discussion of Training and Certification

Before discussing schools of training, the reader should understand the difference between medical societies, training programs and board certification.

Medical societies that require memberships and offer conferences and some training programs are different from formal training programs, medical academies, and medical specialty boards. Societies and their meetings can offer significant information through research presentations, and discussions of current and newer treatment philosophies and technologies. Some of these membership societies even offer basic training courses in different medical specialties. However, these training programs only potentially steer a practitioner into the right direction and further training and education is typically necessary.

True hands-on training programs (residencies and fellowships) and board certification offer a much higher level of education and training. Although awarding board certification in a specialty is the final testament to rigorous training and experience, a significant amount of education can be provided in the board certification process itself. For example, this is the level of education and experience required for preparation for board certification examinations through the ABLS.

For example, a plastic surgeon would say that he/she was trained in the proper residency/fellowship program and then finalized education through the process of the board preparation, examination, and certification. Although this plastic surgeon may attend many conferences and society meetings, he/she would not claim formal training through those societies, or short and basic weekend courses, even though good continuing medical education may be sought through that avenue.

The ABLS encourages the reader to understand the difference between the basic training courses in applications offered in the private/academic sector along with those offered by aesthetic societies (“weekend courses”) versus the intense requirements, training, and education required to apply for ABLS certification and provided by the ABLS through the study, examination, and certification process. This is also true for most board certifications. Some of these courses may offer good basic applications education (to be discussed at the end of this section). However, the ABLS requires more than a weekend course to qualify for the education provided by the ABLS certification process. The ABLS opinion is that further specialty training and certification (in addition to any primary/secondary medical or surgical specialty residency/fellowship training) in LLBD procedures is necessary to properly perform these procedures safely and effectively. The Board recommends this additional training and certification should be required by the applicable state regulatory bodies.

The reader can see an example of the higher level of education from the application requirements and the study materials as described on the ABLS website. One may also read ABLS Diplomate reviews of the high level of education and the value of certification. Many of those physicians who have become ABLS certified are also members of other medical, surgical, and cosmetic societies, and they describe the difference between the society conferences and actual board certification.

Although the ABLS and certain of its Diplomates and board members would be happy to offer assistance in future determinations of training schools and programs, residencies, and fellowships, this is a topic for another document/discussion as there are many detailed facets involved. However, it is necessary to briefly comment in this document about the increasing popularity of “laser training programs” that are offered by physician and non-physician programs.

Laser and Light Training Programs

Although there are well-qualified training programs available (weekend and week-long or greater courses), there are many programs that imply they offer enough basic and advanced training to practitioners who will then need no further training, supervision or certification. For example, some programs offer a “certified laser technician” certification or diploma, but in the Board’s opinion often do not properly train or educate practitioners for delivering efficacious and safe procedures.

Unfortunately, it is commonly thought and accepted by some practitioners that a four-hour-sales-rep training or a “weekend” course in lasers is all that is necessary to begin treating patients. One of the authors has been an expert witness in many cases in which a “certified laser tech” (non-medical person), with no evidence of real medical training, has caused a complication in treating a patient. In some cases it has been discovered that the “laser tech” had in fact no training or supervision and that the patient didn’t know what he or she was getting into. Due to the lack of physician involvement, the patient may not even know what to do, what is expected, or where to report complications.

The ABLS recognizes that regulating these “schools” and training venues would be a large undertaking, but this is an extremely important objective for future initiatives to strengthen training and offer better patient protection and efficacious procedures. The ABLS would be happy to discuss its assistance in the future on this topic. However, the ABLS is currently able to validate that there has been enough training and experience of the practitioner through the ABLS board certification.

In Section 16, Dr. Seiler will give an example of how he trains one of his in-house practitioners to perform laser hair removal.

14. Training Categories

This section describes the training requirements recommended by the ABLS for each practitioner level in each treatment category. This training includes both initial training in basic/advanced laser theory, physics, tissue interaction, safety and the practice of several cosmetic procedures, and the additional training required specific to each treatment class. Physician supervision of non-physicians is also described. A significant portion of the training described below can be accomplished through the study and preparation for the ABLS Written Examinations, with further validation of training through the application requirement checklist and the oral examination. The study materials provided by the ABLS for the examinations include in-depth education on all of these topics. Further hands-on training must be acquired to fulfill the treatment-specific training as described in this section (i.e. the training for each procedure). The ABLS can also recommend hands-on training programs and refer practitioners to physician trainers in the United States.

Categories for training and supervision will be divided into initial and per-procedure training and will be specific to level of practitioner and procedure category:

1. **Initial training** (specific to practitioner level):
 - a. Theory and physics of laser and light/energy-based devices and procedures including effect on living tissue, tissue interaction, clinical applications, pre/post treatment care, etc.
 - 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, recognition/management/reporting of side effects and complications
 - c. LLBD safety
 - d. State Medical Board rules and regulations (this document)

2. **Procedure/Device training** (specific to procedure category/device and practitioner level)
 - a. Device specific training (generally listed in “hours of training”)
 - i. Physics of individual device
 1. Treatment parameters/settings (Power/energy/fluence, pulse width, pulses, pulse delays)
 - ii. Conditions approved to be treated
 - iii. General guidelines for treatment
 - iv. Safety and precaution
 - v. Side effect and complication recognition, management and reporting
 - b. Number of procedures practitioner must observe
 - c. Number of procedures practitioner must perform under observation
 - d. Number of cases performed before less supervision can occur (for non-MDs)
 - e. Higher level supervision by Level 1 and possibly Level 2 practitioner

Initial Training (specific to practitioner level)

The following will discuss initial basic (non-device specific) training for the 4 practitioner levels. It is recommended that this training is obtained specifically for LLBD procedures in residency/fellowship, approved laser training program (weekend/week laser courses), and individual trainings (preceptorships, courses at laser physician's practices, in-house training from Level 1 practitioner to another practitioner). It is recommended that "self-study" does not count for these hours, as the hours suggested must be given and supervised by approved programs and trainers. Initial device sales rep training is usually not sufficient to count for these hours unless given by an approved trainer. The ABLIS is happy to discuss this further to make recommendations regarding how to obtain this training.

1. Level 1 Practitioner (MD/DO)
 - a. LLBD Theory and Physics: 16 hours
 - b. Skin: 16 hours
 - c. Safety: 8 hours
 - d. State Medical Law: 4 hours
2. Level 2 Practitioner (PA/NP)
 - a. LLBD Theory and Physics: 24 hours
 - b. Skin: 24 hours
 - c. Safety: 8 hours
 - d. State Medical Law: 4 hours
3. Level 3 Practitioner (RN/LPN)
 - a. LLBD Theory and Physics: 24 hours
 - b. Skin: 24 hours
 - c. Safety: 8 hours
 - d. State Medical Law: 4 hours
4. Level 4 Practitioner (Aesthetician, Cosmetologist, Laser Tech for limited procedures)
 - a. LLBD Theory and Physics: 48 hours
 - b. Skin: 48 hours
 - c. Safety: 8 hours
 - d. State Medical Law: 4 hours

Procedure/Device Training (specific to procedure category/device and practitioner level)

The following section will list training/supervision rules for each procedure category pertaining to the list in Item 14-2 (a through e) as listed above. This list will determine the following (according to 14-2, a-e):

- a) level of education/training specific to device
 - Section 14-2, a: i.-v. above describes the subcategories of training for each LLBD
 - Hours listed in this category (a) should include training in subcategories (i.-v.). These procedure specific training hours are “in-addition” to the hours for initial/basic training listed above.
 - The next section will list the number of hours of this category of training for each procedure/device specific to each practitioner level, but will not subdivide the hours for the topics to be included (parameters/settings, conditions, treatment guidelines, safety, side effect and complication recognition and management) as it should be understood that all of these topics must be covered in the listed hours of training).
- b) number of procedures the practitioner must observe to begin performing the procedure
- c) number of procedures the practitioner must perform under approved supervision to begin performing without supervision (if allowed)
- d) number of cases performed before supervision can be decreased (in very specific circumstances)
 - NOTE: the “number” listed that the practitioner must perform before “less supervision” as stated can occur is a number of procedures in that specific to each procedure category. Procedures performed in other categories do not count toward that number. The practitioner must have that number of cases in the specific procedure category before being allowed less PMD supervision. Therefore, this should be understood in all following sections (“in this procedure category” is implied after each “number” described).
- e) level of required physician supervision of non-physicians
 - Same note as above regarding procedure numbers

NOTE: The above *procedure/device specific training* for each procedure category is **in addition to** the “Initial Training” for each level of practitioner listed above.

Each of the following Training Categories begin on a separate page for easier reference.

ABLATIVE LASER SKIN RESURFACING

- Note: Ablative Skin Resurfacing is to be performed by Level 1 physicians only.

This category includes: CO2, ER:YAG 2940, and any other ablative (tissue-vaporizing/removing) devices

Level 1 Practitioners

- a) 16 hours each device
- b) 10 cases observed
- c) 10 cases performed under supervision
- d) N/A
- e) N/A

Levels 2-4 cannot perform these procedures. The state medical board could make an exception here for PAs or Nurse Practitioners given a certain level of experience.

NON-ABLATIVE LASER PHOTOREJUVENATION

Lasers for non-ablative photorejuvenation (fractionated and non-fractionated)

This sub-category includes:

- Wavelengths: ER:YSGG 2790, ER:GLASS 1550, 1540, 1064, 1320, 1410, 1440, Thulium 1927, other non-ablative wavelengths
- Some Common Device Names: Fraxel, Pixel, Pearl

Level 1 Practitioners

- a) 16 hours each device
- b) 10 cases observed
- c) 10 cases performed under supervision
- d) N/A
- e) N/A

Level 2 Practitioners

- a) 16 hours each device
- b) 20 cases observed
- c) 20 cases performed under supervision
- d) Number of cases performed before supervision can be decreased
 - a. After 50 cases performed with PMD seeing patient before procedure, practitioner may see and treat patient without PMD seeing patient each time, but must have PMD see patient for initial consult/consent and sign chart for each visit.
 - b. PMD must always see patient in initial consult/consent and initial/first treatment
- e) Level of required physician supervision
 - a. PMD must always see patient in initial consult/consent and initial/first treatment
 - b. PMD must see patient every visit until practitioner has successfully performed 50 treatments
 - c. After 50 treatments, PMD must still chart review/sign each visit

Level 3 Practitioners

- NOTE: Level 3 Practitioner must have at least 1 year of LLBD experience under PMD and must have performed at least 250 LLBD procedures under said PMD to qualify for training in this category

- a) 24 hours each device
- b) 35 cases observed
- c) 25 cases performed under supervision
- d) Number of cases performed before supervision can be decreased
 - a. PMD must always see patient in initial consult/consent and every treatment
- e) Level of required physician supervision
 - a. PMD must always see patient in initial consult/consent and every treatment

Level 4 Practitioners cannot perform procedures in this category (exception may be made by state medical board if the Level 4 Practitioner meets the requirements of the Level 3 as above and applies for approval).

IPL (INTENSE PULSED LIGHT) and BBL (BROAD BAND LIGHT)

Level 1 Practitioners

- a) 16 hours each device
- b) 15 cases observed
- c) 10 cases performed under supervision
- d) N/A
- e) N/A

Level 2 Practitioners

- a) 24 hours each device
- b) 25 cases observed
- c) 25 cases performed under supervision
- d) Number of cases performed before supervision can be decreased
 - a. After 50 cases performed with PMD seeing patient before procedure, practitioner may see and treat patient without PMD seeing patient each time, but must have PMD see patient for initial consult/consent and sign chart for each visit.
 - b. PMD must always see patient in initial consult/consent and initial/first treatment
 - c. After 100 cases, practitioner may be able to see patient without PMD but PMD must be aware of the patient and this must be approved by the state medical board (Level 2 practitioner seeing a patient without the PMD seeing the patient initially).
- e) Level of required physician supervision
 - a. PMD must always see patient in initial consult/consent and initial/first treatment (until otherwise approved as in part c above).
 - b. PMD must see patient every visit until practitioner has successfully performed 50 treatments
 - c. After 50 treatments, PMD must still chart review/sign each visit

Level 3 Practitioners

- NOTE: Level 3 Practitioner must have at least 6 months of LLBD experience under PMD and must have performed at least 150 LLBD procedures under said PMD to qualify for training in this category
-
- a) 24 hours each device
 - b) 35 cases observed

- c) 25 cases performed under supervision
- d) Number of cases performed under supervision
 - a. PMD must always see patient in initial consult/consent and every treatment
- e) Level of required physician supervision
 - a. PMD must always see patient in initial consult/consent and every treatment

Level 4 Practitioners

- NOTE: Level 4 Practitioner must have at least 1 year of LLBD experience under PMD and must have performed at least 250 LLBD procedures under said PMD to qualify for training in this category

- a) 36 hours each device
- b) 40 cases observed
- c) 40 cases performed under supervision
- d) Number of cases performed before supervision can be decreased
 - a. PMD must always see patient in initial consult/consent and before each treatment
- e) Level of required physician supervision
 - a. PMD must always see patient in initial consult/consent and before each treatment

PHOTOEPIILATION / LASER HAIR REMOVAL

These devices include Alexandrite lasers (755nm), Diode lasers (800-810nm), ND:YAG (1064nm), some IPLs.

Level 1 Practitioners

- a) 8 hours each device
- b) 10 cases observed
- c) 10 cases performed under supervision
- d) N/A
- e) N/A

Level 2 Practitioners

- a) 16 hours each device
- b) 15 cases observed
- c) 15 cases performed under supervision
- d) Number of cases performed before supervision can be decreased
 - a. After 25 cases performed with PMD seeing patient before procedure, practitioner may see and treat patient without PMD seeing patient each time, but must have PMD see patient for initial consult/consent and sign chart for each visit.
 - b. After 50 cases performed, practitioner may see and treat patient without PMD seeing patient for initial consult, but PMD must still have a per-patient chart review/signature with practitioner for each patient visit/treatment.
- e) Level of required physician supervision
 - a. PMD must see patient initial consult until practitioner has successfully performed 50 treatments
 - b. PMD must see patient every visit until practitioner has successfully performed 25 treatments
 - c. After 25 treatments, PMD must still chart review/sign each visit

Level 3 Practitioners

- a) 24 hours each device
- b) 25 cases observed
- c) 25 cases performed under supervision
- d) Number of cases performed before supervision can be decreased
 - a. After 50 cases performed with PMD seeing patient before each procedure, practitioner may see and treat patient after initial treatment without PMD seeing patient each time, but must have PMD see patient for initial consult/consent and sign chart for each visit.

- b. PMD must always see patient in initial consult/consent and initial/first treatment
- e) Level of required physician supervision
 - a. PMD must always see patient in initial consult/consent and initial/first treatment
 - b. PMD must see patient every visit until practitioner has successfully performed 50 treatments
 - c. After 50 treatments, PMD must still review/sign chart each visit

Level 4 Practitioners

- f) 24 hours each device
- g) 30 cases observed
- h) 30 cases performed under supervision
- i) Number of cases performed before supervision can be decreased
 - a. PMD must always see patient in initial consult/consent and before each treatment
- j) Level of required physician supervision
 - a. PMD must always see patient in initial consult/consent and before each treatment

VASCULAR AND PIGMENTARY CONDITIONS OR LESIONS

These devices include: ND:YAG and Q-Switch ND:YAG Laser (1064nm), Pulsed Dye Laser (585-595nm), KTP Laser (532nm), Alexandrite (755nm), IPL/BBL (400-1200nm, see also procedure category for this device), Radiofrequency (RF, through a probe for individual lesions)

If a device or category of LLBD is not mentioned in this category but can potentially treat targets of color (i.e. Fraxel, CO2), it is listed in another procedure category with details more specific to its primary function, and therefore the rules per that category apply when treating vascular/Pigmentary conditions/lesions.

Level 1 Practitioners

- a) 16 hours each device
- b) 20 cases observed
- c) 10 cases performed under supervision
- d) N/A
- e) N/A

Level 2 Practitioners

- a) 16 hours each device
- b) 30 cases observed
- c) 30 cases performed under supervision
- d) Number of cases performed before supervision can be decreased
 - a. After 50 cases performed with PMD seeing patient before procedure, practitioner may see and treat patient without PMD seeing patient each time, but must have PMD see patient for initial consult/consent and sign chart for each visit.
 - b. PMD must see patient every visit until practitioner has successfully performed 25 treatments
 - c. PMD must always see patient in initial consult/consent and initial/first treatment
 - d. After 100 cases, practitioner may be able to see patient without PMD but PMD must be aware of the patient and this must be approved by the state medical board (Level 2 practitioner seeing a patient without the PMD seeing the patient initially).
- e) Level of required physician supervision
 - a. PMD must always see patient in initial consult/consent and initial/first treatment (until otherwise approved as in part c above).
 - b. PMD must see patient every visit until practitioner has successfully performed 50 treatments
 - c. After 50 treatments, PMD must still chart review/sign each visit

Level 3 Practitioners

- NOTE: Level 3 Practitioner must have at least 6 months of LLBD experience under PMD and must have performed at least 100 LLBD procedures under said PMD to qualify for training in this category
- a) 24 hours each device

- b) 35 cases observed
- c) 25 cases performed under supervision
- d) Number of cases performed under supervision
 - a. PMD must always see patient in initial consult/consent and every treatment
- e) Level of required physician supervision
 - a. PMD must always see patient in initial consult/consent and every treatment

Level 4 Practitioners

- NOTE: Level 4 Practitioner must have at least 6 months of LLBD experience under PMD and must have performed at least 100 LLBD procedures under said PMD to qualify for training in this category
- a) 24 hours each device
- b) 35 cases observed
- c) 25 cases performed under supervision
- d) Number of cases performed under supervision
 - a. PMD must always see patient in initial consult/consent and every treatment
- e) Level of required physician supervision
 - b. PMD must always see patient in initial consult/consent and every treatment

TATTOO REMOVAL

These devices include: Q-switch ND:YAG (1064nm), Q-switch Ruby (694nm), Q-switch Alexandrite (755nm), Pulsed Dye Laser (585-595nm), certain nanosecond and picosecond tattoo removal lasers

Level 1 Practitioners

- a) 16 hours each device
- b) 15 cases observed
- c) 10 cases performed under supervision
- d) N/A
- e) N/A

Level 2 Practitioners

- a) 24 hours each device
- b) 25 cases observed
- c) 20 cases performed under supervision
- d) Number of cases performed before supervision can be decreased
 - a. After 50 cases performed with PMD seeing patient before procedure, practitioner may see and treat patient without PMD seeing patient each time, but must have PMD see patient for initial consult/consent and sign chart for each visit.
 - b. PMD must always see patient in initial consult/consent and initial/first treatment
- e) Level of required physician supervision
 - a. PMD must always see patient in initial consult/consent and initial/first treatment
 - b. PMD must see patient every visit until practitioner has successfully performed 50 treatments
 - c. After 50 treatments, PMD must still chart review/sign each visit

Level 3 Practitioners

- NOTE: Level 3 Practitioner must have at least 1 year of LLBD experience under PMD and must have performed at least 250 LLBD procedures under said PMD to qualify for training in this category
- a) 24 hours each device
- b) 50 cases observed
- c) 35 cases performed under supervision
- d) Number of cases performed under supervision

- a. PMD must always see patient in initial consult/consent and every treatment
- e) Level of required physician supervision
 - a. PMD must always see patient in initial consult/consent and every treatment

Level 4 Practitioners cannot perform procedures in this category (exception may be made by state medical board if the Level 4 Practitioner meets the requirements of the Level 3 as above and applies for approval).

NON-LASER SKIN REJUVENATION

IR (infrared), RF (radiofrequency), US (ultrasound), other non-laser energy-based rejuvenation devices

Level 1 Practitioners

- a) 8 hours each device
- b) 5 cases observed
- c) 5 cases performed under supervision
- d) N/A
- e) N/A

Level 2 Practitioners

- a) 8 hours each device
- b) 10 cases observed
- c) 10 cases performed under supervision
- d) Number of cases performed before supervision can be decreased
 - a. After 25 cases performed with PMD seeing patient before each procedure, practitioner may see and treat patient without PMD seeing patient each time, but must have PMD see patient for initial consult/consent and sign chart for each visit.
 - b. After 50 cases performed, practitioner may see and treat patient without PMD seeing patient for initial consult, but PMD must still have a per-patient chart review/signature with practitioner for each patient visit/treatment.
- e) Level of required physician supervision
 - a. PMD must see patient for initial consult until practitioner has successfully performed 50 treatments
 - b. PMD must see patient every visit until practitioner has successfully performed 25 treatments
 - c. After 25 treatments, PMD must still chart review/sign each visit

Level 3 Practitioners

- a) 16 hours each device
- b) 15 cases observed
- c) 15 cases performed under supervision
- d) Number of cases performed before supervision can be decreased
 - a. After 50 cases performed with PMD seeing patient before each procedure, practitioner may see and treat patient after initial treatment without PMD seeing patient each time, but must have PMD see patient for initial consult/consent and sign chart for each visit.

- b. PMD must always see patient in initial consult/consent and initial/first treatment
- e) Level of required physician supervision
 - a. PMD must always see patient in initial consult/consent and initial/first treatment
 - b. PMD must see patient every visit until practitioner has successfully performed 50 treatments
 - c. After 50 treatments, PMD must still review/sign chart each visit

Level 4 Practitioners

- a) 16 hours each device
- b) 20 cases observed
- c) 20 cases performed under supervision
- d) Number of cases performed before supervision can be decreased
 - a. PMD must always see patient in initial consult/consent and before each treatment
- e) Level of required physician supervision
 - a. PMD must always see patient in initial consult/consent and before each treatment

ENDOVASCULAR LASER ABLATION (EVLA)

The following Section must follow the State Medical Regulations and Vascular Surgery Board Regulations. The following are suggestions for objective training numbers.

Level 1 Practitioners

- a) 16 hours each device
- b) 20 cases observed
- c) 15 cases performed under supervision
- d) N/A
- e) N/A

Level 2 Practitioners

- a) 16 hours each device
- b) 40 cases observed
- c) 35 cases performed under supervision
- d) Number of cases performed before supervision can be decreased
 - a. PMD must always see patient in initial consult/consent and before each treatment
- e) Level of required physician supervision
 - a. PMD must always see patient in initial consult/consent and before each treatment

Levels 3-4 cannot perform these procedures.

LASER-ASSISTED LIPOSUCTION (LAL) & POWER-ASSISTED LIPOSUCTION

The following Section must follow the State Medical Regulations and Surgery and Plastic/Cosmetic Surgery Board Regulations. The following are suggestions for objective training numbers.

These are surgical procedures and the performance of should follow state surgical procedure laws. The following is the suggestion of the ABLs.

- Practitioner Level 1 (physician) only
- Laser or energy (water, US, heat) assisted invasive liposuction
- 1064nm, 1320nm, 1440nm, 1444nm, 924/975nm, 1319nm, Ultrasound
- VaserLipo, Smart Lipo, Cellulaze, Cool Lipo, Tickle Lipo, Accusculpt, Slim Lipo, ProLipo, CelluSmooth, BodyJet (water-assisted).

Level 1 Practitioners

- a) 16 hours each device
- b) 20 cases observed
- c) 15 cases performed under supervision
- d) N/A
- e) N/A

Levels 2-4 cannot perform these procedures.

LASER ASSISTED SURGERY

The following Section must follow the State Medical Regulations and Surgery and Plastic/Cosmetic Surgery Board Regulations. The following are suggestions for objective training numbers.

This category includes any laser or other light/energy based device used in surgery. These are surgical procedures and the performance of should follow state surgical procedure laws. The following is the suggestion of the ABLs.

- Practitioner Level 1 (physician) only
- Generally lasers used to assist surgeons with cutting, coagulation, tissue removal and ablation, etc.
- Most common lasers are CO2, ND:YAG, Erbium

Level 1 Practitioners

- a) 16 hours each device
- b) 20 cases observed
- c) 15 cases performed under supervision
- d) N/A
- e) N/A

Levels 2-4 cannot perform these procedures.

Future items regarding the above training specifics to be discussed on an individual basis with each respective board:

- Can a PA at some advanced level of training and experience with certain non-ablative lasers and IPL, vascular/pigment lesions, and tattoo removal not have to have PMD in consult and/or initial treatment like in some of the other categories (LHR)?
- Can a PA at some advanced level of training and experience serve as supervisor over level 3 at some point for certain procedures, after a certain amount of experience under that PMD and a certain number of cases?
- Do we consider lessening the number of hours/cases for “new procedures” once a practitioner has done a certain number? For example, if they buy a new LHR device etc. or if they buy a new piece of equipment (different type) but have the proper experience, maybe they don’t need as much training on that “new” device which is really just an upgrade or “better” version/model?
- Hopefully the description of the level of physician involvement in these categories understandable and sufficient. More can be discussed on this topic, but also included in this

“package” of documents will be log sheets, proof of training and cases, and delegation protocols describing MD involvement and practice and the example of how to train and supervise a practitioner.

15. Yearly Minimum Training and Number of Procedures

Each practitioner must have a minimum number of hours of continuing LLBD education and a minimum number of cases performed per year to qualify for yearly re-certification and approval by the individual State Medical Boards to continue treating patients with LLBD procedures. If these minimums are not met per year, the practitioner must undergo another full “initial” training and “procedure category specific” training to be approved to treat patients.

- Yearly continuing LLBD education hours may include:
 - Official CME hours
 - LLBD specific medical conference hours
 - Online study and courses
 - ABLS and State Medical Board approved courses
 - Self-Study through online webinars, lectures, CME courses
 - With approval, may include hours lectured by PMD if the PMD is a primary LLBD practitioner (in-house LLBD education hours)
- Yearly continuing LLBD education may be in general for all LLBD procedures and does not have to be hours per device (i.e. the required “one-time” per year regardless of how many procedures the practitioner is qualified to perform).
 - Hours should include training on:
 - LLBD Theory and Physics
 - Skin anatomy and conditions/diseases
 - Safety
 - Treatment of conditions
 - Recognition, management, and reporting of side effects and complications
 - Overall use of LLBD procedures to treat patients
- Yearly minimum number of cases pertains to each LLBD procedure (practitioner must have the minimum number of procedures performed per year for each individual category of procedures).

Yearly Minimum Continuing LLBD Education Hours

1. Level 1 Practitioners: 8 hours
2. Level 2 Practitioners: 16 hours
3. Level 3 Practitioners: 24 hours
4. Level 4 Practitioners: 36 hours

Yearly Minimum Number of Cases Per LLBD Category

1. Level 1 Practitioners: 10 procedures in each procedure category practitioner is certified
2. Level 2 Practitioners: 15 procedures in each procedure category practitioner is certified
3. Level 3 Practitioners: 35 procedures in each procedure category practitioner is certified
4. Level 4 Practitioners: 50 procedures in each procedure category practitioner is certified

Yearly Minimum Number of Total Cases

1. Level 1 Practitioners: 10 minimum total procedures per year
2. Level 2 Practitioners: 15 minimum total procedures per year
3. Level 3 Practitioners: 35 minimum total procedures per year
4. Level 4 Practitioners: 50 minimum total procedures per year

16. Recommendations Relative to Regulatory Structure

The following are additional recommendations from the ABLs on several critical topics:

Utilize an LLBD Specialist on Each State Medical Board of Examiners

The practice of laser medicine and surgery (to include all LLBD procedures) requires specific knowledge of both the medical procedures and the technology. Therefore, the ABLs is offering this document to assist FSMB and State Medical Boards in both understanding how lasers and light are the practice of medicine, and what regulations and oversight make sense. Laws and regulations should become standardized with each individual State Medical Board following the recommendations in this carefully researched and constructed document. Due to the complicated nature of LLBD specialties, the ABLs recommends that FSMB and each State Medical Board has, as one of its council members/advisors, a specialist in the field of laser medicine and surgery. The Chief Author of this document, Warren B. Seiler III, MD, would be pleased to assist in this area as an advisor to the FSMB and State Medical Boards, and can assist each State Board in selecting a qualified practitioner.

Develop Plans and Tools to Implement New Regulations

Plans should be developed to bring about the changes the ABLs believes are necessary. Initially, the main course of action would be to make physicians and practitioners aware of both current and new guidelines. A State Medical Board could use the help of the approved LLBD Specialist to compile a list of current practices and other facilities utilizing LLBD procedures. Notification of new guidelines can then be made and with a stated timeframe to become compliant with both current and new guidelines. A “grandfathering-in” policy for certain current practitioners can also be determined, based on needs and/or requests. Discussions can also occur regarding increasing patient awareness of how they can be more safely and effectively treated.

Implement Process to Discuss and Evaluate Complaints and Complications

The Board recommends that a process be set in place to investigate and evaluate complaints to the State Medical Boards. Currently, many patients do not know this process is available, usually due to not knowing of the need for physician involvement. This document provides the basis, as it has defined the proper use of LLBD procedures, proper practitioner level, training and supervision required, and will enable the State Medical Boards to better evaluate patient complaints. In addition, examples of acceptable and unacceptable side effects and complications are discussed below. The State Board’s Laser Specialist can assist the State Board to evaluate the problem and help prescribe an appropriate course of action. The Laser Specialist could also regularly meet with a State Medical Board Legal Counsel to help with any issues at hand.

Leverage the Value of Expert Evaluators/Witnesses

Due to the rise in complications and complaints to the State Medical Boards and to local attorneys, there are currently a number of Laser Specialists in the country who act as Expert Evaluators and Expert

Witnesses. Dr. Seiler is one of these and therefore understands the role they can play in assessing complaints. These practitioners can be utilized in addition to the State Medical Board's own Laser Specialist Advisor to help evaluate events and complications.

Define and Recognize Acceptable Versus Unacceptable Events

Although it is very difficult to describe a complete list of acceptable and unacceptable results, side-effects, and complications for each procedure, the following is a general description. The State Medical Board's Laser Specialist can help to further define these and help assess individual cases. Most LLBD procedures have an acceptable range of erythema (redness of the skin or rash), edema (swelling), healing time, and good/expected result after each treatment. This is something that should be part of the knowledge of the physician and non-physician practitioner. It is beyond the scope of this document to comment in detail on "good/expected" results; however this is an area where the Laser Specialist on each State Board can offer expertise, for example what level of side-effects and downtime is acceptable in reported complications and patient complaints.

- Less invasive treatments including non-laser skin rejuvenation, laser hair removal, some IPL procedures, and photorejuvenation carry an acceptable minimal to few days of mild to moderate erythema and edema. Blistering is generally not common or expected, and burns are not acceptable.
- Mid-level treatments, such as higher-output IPL procedures and laser spider vein and tattoo removal treatments, may result in more edema and bruising. In general, blistering is not expected, and ulceration and burns are not acceptable.
- Fractional non-ablative procedures which involve higher power levels, may carry a few days to a week of erythema and edema, but blisters are evidence of over treatment, and burns are not acceptable.
- Fractional and non-fractional ablative procedures, including skin resurfacing, will have the highest level of downtime, generally 3 days to a few weeks of erythema and edema. These procedures require a higher level of post-procedure skincare and follow-up management. Skin sloughing and major "pigment shedding" are generally accepted, but burns are not acceptable.

Although this is not a comprehensive list and greater detail can be provided as requested. The ABLB would be pleased to help in determining an acceptable level of result and downtime so that the State Boards have a reference point in evaluating issues. A following section provides specific examples of complications and burns.

Include LLBD Procedures as the Practice of Medicine

This document has discussed the need for recognizing that the practice of LLBD procedures is a separate medical specialty, and should not be bound together with "cosmetics" in general which can include everything else from chemical peels, to liposuction, to simple facial treatments. This document has also

discussed the need to oversee the use of the word “medical”, “med” (or other form) in practice names, documentation, advertising, and other uses. LLBD procedures constitute the practice of medicine and should be regulated as such. These procedures are treating an organ of the body, namely the skin and its anatomical parts. Diagnosing and treating the conditions of the skin, whether medical conditions or cosmetic concerns, requires extensive knowledge of the skin, its anatomy and diseases, and how products and procedures can treat and affect the skin.

The proper treatment of patients also requires the knowledge necessary to manage treatments and their possible side effects and complications. The physician practitioner must also be able to recognize possible cancer and skin conditions/diseases that may affect the use of these procedures or their outcomes; or alternatively the non-physician practitioner must have the ability to have the patient evaluated by the responsible supervising physician. Pre-existing conditions/diseases that can affect outcome of the procedures can be missed by the under-trained practitioner, or one that does not have the proper supervision of an LLBD-trained physician. It has become more common that the treatment of side effects and complications is less than satisfactory due to the lack of knowledge and training of certain practitioners who are performing these procedures outside of the guidelines in current state laws and/or as stated in this document. Therefore, the guidelines set forth in this document regarding practitioners, training, and supervision are based on the practice of medicine.

Categories of Burns

The following is a brief description of burns that can occur as a result of improper use of LLBD procedures.

There are 4 basic categories of burns.

1. **First degree burns** are superficial burns that affect the outer layer of the skin (epidermis)
 - Red without blister
 - Usually dry
 - Mild to moderate pain
 - Usually heals within a week
 - Usually no long term or permanent effect or scar (no noticeable sign after healed)
 - Requires superficial skincare management
2. **Second degree burns** are partial thickness burns (superficial or deep) that extend into the dermis
 - Superficial Partial Thickness (papillary dermis)
 - i. Red with clear blister
 - ii. Usually moist
 - iii. Very painful
 - iv. 2-4 weeks to heal
 - v. Increased risk of infection/cellulitis but usually heal without scarring
 - vi. Requires moderate wound care

- Deep Partial Thickness (reticular dermis)
 - i. Yellow/white, may blister
 - ii. Usually mostly dry
 - iii. Uncomfortable to painful
 - iv. 1-2 months to heal
 - v. Increased risk of infection
 - vi. Likely scarring, skin contracture, hypo/hyperpigmentation, discoloration
 - Generally long lasting or permanent scar and/or discoloration
 - vii. Requires more extensive wound care
3. **Third degree burns** are full thickness burns, destroying epidermal and dermal layers and extend into the subcutaneous tissue
- White/brown without blanching
 - Tough/leather appearance
 - Generally painless
 - Multiple months to heal
 - Heals by scarring, contracture, discoloration
 - Generally permanent scar and discoloration
 - Requires extensive wound care by a burn wound specialist
4. **Fourth degree burns** (separate category in most sources) extends into the fat, muscle, and bone
- Charred black eschar
 - Dry, painless
 - Requires excision, amputation
 - Severe functional impairment
 - High risk of infection and complication, even death
 - Requires extensive surgical and wound management

In general, *no LLBD procedure should result in a burn*. However, superficial first degree burns can occasionally occur even when the procedure is performed by a well-trained practitioner, and if the burn wound is properly treated and no scarring occurs, this would not necessarily cause suspicion of mistake or negligence. Reasons for this include an undiagnosed or unforeseen problem with the patient's skin that made him/her more susceptible to complication from a normal treatment. Another reason would be slight over treatment of the skin in cases where the treatment parameters would be considered within normal limits, but a particularly sensitive patient was treated. Finally, the patient may not adhere to the pre/post procedure instructions that should limit the risk of side effects and complications, and therefore put him or herself at risk for complications. If these types of problems occur and are properly managed, and the practitioner takes proper steps to avoid such problems in the future, then it is a

learning experience and no major harm is done. However, if these types of complications happen more than rarely, investigation into the practice and practitioner would be recommended.

Second and third degree burns are much more likely caused by the practitioner's improper use of a device and its settings, or misdiagnosis of a known reason to either alter treatment, or to not treat the patient (i.e. the patient was too tan to be treated but the practitioner treated him/her anyway). Second degree burns would be considered "almost never acceptable" and third degree burns *are never acceptable*. Serious degree burns can occur in the following ways:

1. Use of the wrong device in treating a particular concern/condition or patient skin color. For example:
 - a. Using an IPL device on an African American (darker skin absorbs light energy faster)
 - b. Using a laser hair removal device on a tattoo (the power is not matched to the need)
2. Use of a proper device but with settings that are too aggressive (these settings include overall energy, power density for the area treated, pulse duration, and the number of pulses per unit of time)
3. Improper technique (too many pulses on the same area or too much overlapping of pulses)
4. Treatment of a patient who should not be treated (too tan, too dark skin, missed skin condition putting the patient at risk for complication, misdiagnosis of a pre-existing condition, a patient is not properly shaved before certain treatments, a patient is taking certain medications/topicals such as Retin A that should have been discontinued before treatment, etc.)
5. Improper before-and-after care and instructions to the patient

The practitioner must be aware of the above information and have the ability to treat the possible complications. He/she must also have the ability to immediately refer the patient to a trained specialist for more complicated burns. No practitioner should treat a patient with a procedure or device if he/she is not able to recognize the possible complications or those issues/conditions that might make the patient more susceptible to complication. All practitioners must be able to properly manage complications. Knowledge of burn wound management should be part of the Initial Training and the Individual Device Training as listed in the Training section of this document.

Recommendations for Limitation of Level 4 Practitioners

This document's Training Section outlines the guidelines for Level 4 Practitioners, but extra comment is necessary to summarize the ABLS opinion on the incorporation of these practitioners in practices that offer LLBD procedures. Level 4 practitioners are non-medical persons who have increasingly started to perform these procedures. They are generally Aestheticians, Cosmetologists, "certified laser technicians", or others who generally have no formal medical training or LLBD training. The "certified laser technician" (or CLT) has already been described in this document as one to be very cautious about, as it is the opinion of the ABLS that CLT certificates can be obtained with as little as a few hours of training or mean little more than "certification of attendance" at a seminar. For example, Dr. Seiler is currently an expert witness in a case in which an aesthetician burned an African American patient with an IPL device (she should never have used IPL on an African American patient). The aesthetician didn't even know how to properly determine patient's skin type suitability. This is as basic as one can get in understanding skin and applicable equipment and procedures. She also claimed she was a "certified laser technician". It was discovered that she simply "attended" a 4-hour course in another state where

aestheticians cannot use IPL devices. Therefore, she received an essentially worthless sheet of paper claiming that she “attended” the training, but in fact had no adequate training or education to perform the IPL procedure.

Level 4 practitioners can be utilized to treat patients, but must have both the training as recommended in this document and the proper physician supervision. Therefore, these practitioners should only be used for the approved procedures in practices in which the physician specializes heavily in LLBD procedures so that proper supervision is actually accomplished. An experienced aesthetician can be a proper functioning Level 4 Practitioner. Podiatrists, chiropractors, and all other non-MD/DO practitioners (not including Level 2-3 practitioners) do not in the Board’s opinion have sufficient core LLBD training to put them in Level 4, and even if appropriate LLBD training occurs, these practitioners should not be considered above a Level 4. Grandfathering-in of current Level 4 Practitioners (aestheticians, cosmetologists, laser technicians) may be accomplished by meeting sufficient training requirements. The ABLIS is available to provide further details upon request.

Example of in-house training by Dr. Seiler of a nurse or aesthetician (“practitioner”) to perform laser hair removal

This is an example of how a Level 3 or 4 practitioner (“practitioner”) would become trained to perform laser hair removal (LHR) in Dr. Seiler’s practice (described in Dr. Seiler’s first person point of view). Although the training described in this example is more than the “minimum” training requirements described in this document, the reader will understand why this is important after reading this section and the comments from the trained nurse at the end.

As a physician specializing solely in laser procedures and injectables, I performed all of the laser procedures myself for the first six years of my practice. Through these years, I feel that I perfected my techniques and quality care of my patients. As my practice grew, I decided it was time to train an experienced nurse and aesthetician to perform laser hair removal as I believed this could be safely administered with the right training and supervision, and would allow me to focus on more ablative procedures.

The first practitioner to be trained was an assistant for three months before being considered. This allowed her time to gain the knowledge of the cosmetic laser field and to properly consult and take care of patients, before beginning to train in actual procedures. She had 17 years of previous experience in the cosmetic medical and surgical field and several years involving the use of lasers (some performed by her) at two other practices. During this time, she observed over 60 LHR treatments along with hours of didactic training and lectures in laser theory, physics, treatments and specific devices. This was in addition to the education she received with each case she observed. As she began her practical (physical) LHR training, we had multiple sessions using minimal power on staff members to train her in the proper technique. Then, she began to treat staff members and several other people under my direct supervision. Each time, we discussed laser parameters, how to diagnose the skin type and choose proper settings, while training in the physical application of the device.

Following this introductory period, she then began to treat patients, and again only under my direct supervision. I determined it was necessary to supervise her treatments until we both felt she could perform them as well as I could. I continued to initially consult with each patient and then she and I would discuss treatment parameters each time the patient received a treatment. She was pleased with my philosophy and agreed my supervision simply ensured proper and safe treatment of the patient.

It is essential to understand that even LHR procedures take much more than buying a device, undergoing a 4-8 hour sales rep or “company trainer” training day, and then handing off the procedure

to a practitioner. Unfortunately, this happens all too frequently. In addition, even the physician needs significant training and experience to master the procedure. Safety and efficacy are the key goals.

Some physicians consider LHR to be “lower” on the totem pole of difficulty of laser procedures. That said, even more invasive (ablative) procedures can be handed off with lack of sufficient training. When this happens, patients are being mistreated, and we need to strengthen the laws governing these procedures.

CMLSO from the Board of Laser Safety and the Laser Institute of America

The ABLS has a relationship with the Board of Laser Safety (BLS) and the Laser Institute of America (LIA) through the relationship with Gus Anibarro, the Director of Education at the LIA. This organization and institute offers didactic and hands-on safety training courses of different levels. The Certified Medical Laser Safety Officer (CMLSO) training and certification offers a high level of education in the field of medical laser safety. Although the ABLS focuses heavily on safety in its written and oral study materials and examinations, the CMLSO is a great hand-on certification. As the purpose of this document is to provide all means necessary to direct regulations, training, safety, and quality of care, the ABLS highly recommends the requirement of a CMLSO certification in each laser practice.

17. About the American Board of Laser Surgery

Why the American Board of Laser Surgery Is Unique

The ABLS is different than most medical specialty boards, in that lasers are utilized in many medical and surgical specialties. It has been said by some that no other board is founded on a device (i.e., the laser). That is not so, because the American Board of Radiology and the American Board of Nuclear Medicine are both founded on devices: the CT scanner and the gamma camera and its tomographic variants.

Actually "the laser" is a misnomer, because there are many different types of lasers used clinically, differing in wavelength, temporal mode of operation, power output, and method of beam delivery. Only lasers are capable of cutting, coagulating, ablating, and welding living tissue by one or more of these three distinct biophysical phenomena: photochemolysis, photopyrolysis, and photoplasmolysis. These are complex processes, totally unlike the effects of scalpels, saws, drills, and electrosurgery, and when used improperly can seriously burn and even maim a patient for life.

Today, laser surgery is not taught in most medical schools, medical/surgical residencies, or fellowship programs. It is learned primarily in postgraduate education, much of which is offered by laser manufacturers themselves. There are unfortunately many scalpel-skilled physicians who are not fully qualified to use lasers in surgery, despite that these are dangerous machines that require specialized knowledge of laser physics and training in order to be used safely.

In the early years of the Board, most of the candidates were from the traditional specialties using lasers: otolaryngology, head-and-neck surgery, ophthalmology, general surgery, gynecology, neurosurgery, gastroenterology, pulmonology, thoracic surgery, etc. In recent years, the majority of candidates have been those who have transitioned from their original specialties into dermatology, plastic surgery, cosmetic surgery, and similar activities in order to escape the challenges of dealing with third-party payers and HMOs. Such specialty jumping has often occurred without adequate training in the cosmetic field, and numerous iatrogenic injuries to patients have resulted. Diplomates of the ABLS, however, have seldom been targets of litigation, because of the education necessary to receive certification from the Board.

In the first decade of the Board's existence, most Diplomates came from the United States and Canada. In recent years, however, many more have come from the international arena including Iraq, Iran, Jordan, Egypt, Colombia, India, Thailand, Japan, Taiwan, Hong Kong, Malaysia, Singapore, Australia, United Kingdom, Saudi Arabia, Kuwait, and others. The chief author of this document has personally board examined candidates from eleven countries. The physicians from these overseas countries have sought certification from the ABLS to strengthen their knowledge and quality of care for their patients; they do not currently have such a certifying board specifically for laser and light procedures in their own countries. Diplomates of the Board are also members of other medical societies and organizations such as the ASLMS, AACS, ASPS, ASDS, AAD, among others.

No other organization aside from the ABLS offers board credentialing in laser and light science and safety in medicine and surgery at this time. The ABLS is the sole medical specialty Board that offers the rigorous study, and written and oral examinations necessary for full Board certification for 30 years.

The ABLS certifications include:

- Full Diplomate status for physicians (passing the full written and oral examinations) in either traditional non-cosmetic specialties, or cosmetic laser and light procedures

- Certificate of Added Qualification for Cosmetic Procedures
- Diplomate with Distinction
- Certificate of Qualification for non-Physician Practitioners

The ABLS is a non-profit 501(C)6 organization registered in the State of Wisconsin.

18. History and Mission of the ABLS

The American Board of Laser Surgery was founded in 1984 by physicians and other medical practitioners from various fields experienced in the basic science and clinical applications of lasers. They shared a concern for the safe and efficacious use of lasers in medicine and surgery. They believed that the increasing complexity and utilization of lasers in treating patients had created a need for the establishment of minimum standards of knowledge, competence, and experience for those who used lasers in the health sciences. Many individual physicians, hospital administrators, chairmen of credentialing committees, and other concerned persons expressed a desire for an organization that would fulfill these needs. In doing so, they recognized that lasers are sophisticated instruments requiring special knowledge and experience for safe, effective use in surgery and therapy.

From the very beginning of the era of lasers in clinical use, iatrogenic, laser-related injuries and deaths were occurring among patients. This was the incentive for the founding of the American Board of Laser Surgery.

The Board's objectives are:

1. To establish levels of knowledge and clinical experience which demonstrate a competent understanding of physics, biophysics and clinical safety for those medical practitioners across medical specialties who utilize lasers and other light-based technologies.
2. To provide study materials and conduct examinations in the physics, biophysics and clinical use and safety of lasers and other light-based technologies, for qualified applicants seeking certification by demonstration of their knowledge in the medical use of these technologies relative to the competent understanding as defined by the Board, and to award Certification based upon successful completion of the Board's study processes and written and oral examinations.
3. To educate as many qualified applicants as possible whom the Board judges, based on their credentials, can benefit from the certification program to become more knowledgeable in the use of lasers and light-based devices, and thereby increase the chances of their efficacious and safe use of these devices in treating patients.
4. To provide, as may be beneficial in the Board's judgment, current information relevant to efficacious and safe applications of lasers and other light-based technologies, to applicants for certification, Diplomates of the Board, medical institutions, governing authorities and/or the general medical community.

The Board's Officers and Directors are well recognized practitioners in their respective fields and teach, train, and lecture internationally on a variety of topics related to the practice of laser medicine and surgery.

19. ABLS Certification

The ABLs educates and certifies both physicians and non-physician medical practitioners in the use of LLBD procedures, in cosmetic and non-cosmetic disciplines. This education is according to the level of practitioner for the different types of procedures. These certifications are based on vetting of applications, provision of comprehensive study materials to qualified applicants – some of which are proprietary to the Board – and rigorous written and oral examinations. We have numerous Diplomates worldwide who can attest to the value of the ABLs certification process.

With the rise in the number of different LLBD procedures, the ABLs has recently changed its cosmetic certification process to be LLBD procedure-category specific. The level of practitioner is listed on the certificate by virtue of the degree (MD, PA, RN, etc.). Practitioners can receive certification in one or more of these overall procedure categories: Cosmetic Laser Surgery, Dermatologic Laser Surgery, or Cosmetic (or Dermatologic) Laser Procedures for a practitioner who does the majority of either invasive (covers all) or non-invasive procedures (e.g., laser hair removal, tattoos, photo-rejuvenation). For a practitioner who performs only a few specialties, the certificate will reflect only one or more that are relevant from below:

- Ablative Laser Skin Resurfacing
- Non-ablative Laser Photo-Rejuvenation
- Photoepilation / Laser Hair Removal
- Vascular and Pigmentary Conditions or Lesions
- Tattoo Removal
- Non-laser Skin Rejuvenation
- Non-invasive Body Contouring
- Endovascular Laser Treatment
- Laser Assisted Liposuction (LAL)
- Laser Assisted Surgery (LAS)

There are three steps to earning the Board's Certification: (1) submitting an Application Form; (2) receiving and assimilating the study materials for the Written Examinations, which can be taken at any time online within one year of receipt of the study materials; and finally (3) sitting for the Oral Specialty Examination, which is designed to evaluate the candidate's clinical experience.

The study materials and textbooks were developed and selected by members of the Board for the purpose of specifically advancing knowledge. The Study Materials and the Written Examinations are truly unique, and the ABLs is currently the only medical specialty board worldwide that offers certification in laser medicine. These materials and exams are regularly updated by the ABLs Board members and other Diplomate contributors.

20. Sample Forms

The following forms are available upon request as a reference and for use by State Medical Boards and practitioners.

1. Protocols for Procedures, Delegation, Safety
2. Procedure log sheets
3. Proof of completed training forms to submit to state boards
4. Patient intake
5. Procedure consent
6. Treatment sheets
7. Before/after instructions

Disclaimer: the ABLS and this document's authors provide these examples "as is" for reference only for educational purposes, and does not recommend these to necessarily be adopted as is by any practice; rather all state boards and practitioners should evaluate and determine their specific needs, and adopt such forms and information that they believe is in the best interest of their patients, and also comply with applicable local regulations regarding their use of laser and light-based devices in medical procedures."

21. Document Authors

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Appendix – About ABL Recognition

The ABMS is (according to their website) "...a not-for-profit organization, assists 24 approved medical specialty boards in the development and use of standards in the ongoing evaluation and certification of physicians. ABMS, recognized as the "gold standard" in physician certification, believes higher standards for physicians means better care for patients."

The American Board of Laser Surgery was founded in 1984 as a not-for-profit 501(C)6 corporation (registered in Wisconsin), as no similar organization existed within the ABMS at that time, nor exists today. There is no one "specialty" that oversees the education and standards of the use of lasers and light-based technologies.

The ABL is the premier and only medical specialty board in the world that champions this cause. We provide in-depth education on lasers and physics and administer both rigorous written and oral examinations. As such, all medical specialties are welcome that use lasers and light-based devices. Since 1984, over 500 physicians have managed to complete the rigorous, complex and extensive studies and examinations required to obtain the certification of ABL Diplomate.

The ABL applied for recognition by the ABMS in the early 1990s and met its qualifications. ABMS has chosen however to recognize only 24 major boards in its history, and has not recognized any additional boards in over two decades, including the well-respected American Board of Cosmetic Surgery (ABCS). The ABL considers this may be "political" in nature. There are over 200 established medical boards not recognized by the ABMS, many of which like the ABL provide valuable service to the medical community and the public at large.

When the ABMS began, it granted itself recognition and the power to determine what is "appropriate" medical care to guarantee public safety, and the ability to issue sanctions to those who do not practice within their standards. The ABMS is, in the ABL's opinion, a more "pro public" rather than "pro physician" organization.

The ABMS may choose to never issue standards or recognize the use of lasers and light. The ABL respectfully submits that education and a manner of measuring education in the use of these tools, safely and effectively, is even more needed today as when the ABL was established 30 years ago. The majority of our medical members have their original boarding with the ABMS. The ABL recognizes additional training beyond what the ABMS is able to certify. Over 500 physicians have become Diplomates of the ABL, attesting to its acceptance and respect in the industry.

The Board also provides the only online List Serve that offers the opportunity for laser practitioners world-wide to share knowledge about science, safety and clinical applications of lasers and light-based technologies. We currently have well over 250 members and growing in this unique knowledge share network, which is described fully at http://americanboardoflasersurgery.org/abls_list_serve.html

The ABL will continue to welcome practitioners from all specialties the world over who wish to obtain an in depth understanding of the use of lasers and light, safety, biophysics and tissue interaction, and demonstrate that understanding in both written and oral exams.