TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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COMMISSIONER

Report on Regulation of Laser Hair Removal

CHARGE

Study the licensing and certification of laser hair removal facilities, including federal statutes and regulatory requirements as well as training for individuals performing laser hair removal procedures.

Executive Summary

The number of facilities offering to remove unwanted hair through the use of lasers or similar medical devices is growing in Texas, leading to a discussion about the appropriate regulatory scheme for this practice. Physicians, including those associated with this practice, are regulated by the Texas Medical Board. Devices such as lasers and Intense Pulsed Light Devices (IPLs) are regulated as medical devices jointly by the Department of State Health Services (DSHS) Drugs and Medical Devices Group and the U.S. Food and Drug Administration (FDA). These devices are also regulated by the DSHS Radiation Group because they emit non-ionizing radiation. Accordingly, the regulatory scheme for these devices is complex and detailed.

Legislation was introduced during the last two sessions to regulate the personnel who operate these devices and the facilities in which they are located. In the 79th Legislature, Rep. Vicki Truitt introduced HB 3178. The House Committee on Public Health received an interim charge to examine the regulation of this practice and submitted its report. In the 80th Legislature, Rep. Truitt and Rep. Jim Jackson introduced HB 174 and Rep. Byron Cook introduced HB 3368 to address this topic. However, neither the 79th nor the 80th Legislature adopted legislation to address the issues raised by these bills. Finally, on June 15, 2007, Rep. Warren Chisum wrote to request that DSHS study the licensing and certification of laser hair removal facilities, including federal statutes and regulatory requirements as well as training for individuals performing laser hair removal procedures. This document constitutes DSHS' response to Rep. Chisum's request.

Facilities engaged in the removal of unwanted hair using lasers or similar medical devices, such as IPL devices, seek to achieve stable long-term or permanent hair reduction through selective targeting of melanin in the hair follicle. The lasers and IPL devices used by these facilities are approved by the FDA for use in performing general and plastic surgery and other dermatological procedures in addition to hair removal.

Due to the potential for harm to the patient and the level of supervision necessary for the safe use of these devices, the FDA requires that these lasers and IPLs be marketed as prescription devices, subject to state controls necessary to ensure that the devices are sold to and used by or under the supervision of specified licensed practitioners. As such, facilities performing laser hair removal procedures must comply with federal and state regulatory requirements designed to protect the health and safety of patients undergoing these procedures.

Current Regulatory Scheme

Federal Regulation

Overview

Lasers and IPLs used to achieve stable long-term or permanent hair reduction are medical "devices" as defined under the Federal Food, Drug and Cosmetic Act (Federal Act). A "device" as defined under 201(h) of the Federal Act, is "an instrument, . . .which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease in man, . . .or to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

Manufacturers, distributors and users of these lasers and IPLs must comply with the applicable provisions of the Federal Act. These requirements include: (a) complying with labeling and use restrictions for prescription devices; (b) obtaining premarket clearance[1] prior to introducing a device into commerce; (c) adhering to any special controls required as a result of the classification assigned to a device; (d) conducting clinical investigations[2] of unapproved devices in accordance with regulations; (e) conforming to federal performance standards established for lasers and IPLs; and (f) reporting serious injuries or deaths associated with a device as required by the medical device reporting regulations.[3]

Prescription Devices

Lasers and IPLs used to achieve stable long-term or permanent hair reduction are "prescription devices." A prescription device, as defined by 21 Code of Federal Regulations (CFR) 801.109, is a device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which 'adequate directions for use' cannot be prepared."

A prescription device may be used if all the following conditions are met: "(a) the device is: (1). . .(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and (2) Is to be

sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice." Since these lasers and IPL devices are limited to prescription use, the label of such devices must contain the statement, "Caution: Federal law restricts this device to sale by or on the order of a _____", the blank to be filled in with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any practitioner licensed by the law of the State in which (s)he practices to use or order the use of the device.

A laser or IPL device determined by FDA during a premarket clearance process to be a prescription device is also a restricted device requiring restricted sale, distribution, or use only upon the written or oral authorization of a practitioner licensed by law to administer or use the device or upon such other conditions as the determined by FDA. State law cannot change the federal determination of whether a device is a prescription device.

Performance Standards for Electronic Products

FDA regulates radiation-emitting electronic products, such as lasers and IPL devices, in order to prevent unnecessary exposure to radiation due to the use of these products. There are specific requirements (performance standards) that apply to these radiation-emitting electronic products. If the electronic product is also a medical device, the product must also comply with the medical device regulations. Lasers and IPL devices indicated for stable long-term or permanent hair reduction must also comply with the applicable requirements in 21 CFR Subchapter J – Radiological Health, including requirements for medical laser products in 21 CFR 1040.10-1040.11.

Device Classification

Under Section 513 of the Federal Act, the FDA has established classifications for approximately 1,700 different types of devices and grouped them into 16 medical specialties referred to as panels. Each of these 1,700 types of devices is also assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. The three classes and the requirements which apply to them are:

Class I: General Controls

Class II: General Controls and Special Controls, some Premarket Approval

Class III: General Controls, Special Controls, and Premarket Approval

Device classification depends on the intended use of the device and also upon indications for use. In addition, classification is risk based, which means that the risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk. All lasers and IPL devices that are known to have received premarket clearance for stable long-term or permanent hair reduction have been assigned a Class II designation by FDA pursuant to regulation by 21 CFR 878.4810---Laser surgical

instrument for use in general and plastic surgery and dermatology.

Texas Regulations

DSHS

Lasers and IPL devices are regulated under three statutes by DSHS. Because they are prescription medical devices, the use and possession of the devices are governed by the Texas Dangerous Drug Act, Chapter 483, Health and Safety Code. Additionally, the manufacture, distribution, sale, advertising, and use of these devices are regulated under the Texas Food, Drug, and Cosmetic Act, Chapter 431, Health and Safety Code. Finally, because the devices are radiation-emitting electronic products, the possession and use of the devices are regulated under the Radiation Control Act, Chapter 401, Health and Safety Code. While each of these statutes addresses a specific aspect of public health and safety, they include similar requirements regarding the controls necessary for possession and use of these devices. The requirements of these chapters and the regulations adopted thereunder specify that the devices must be used under the supervision of a practitioner. A practitioner in Texas is defined as a physician, dentist, optometrist, podiatrist, or veterinarian (Section 483.001(12), Health and Safety Code).

Texas Medical Board

The Texas Medical Board (TMB) licenses and regulates physicians under the authority granted to it in the Medical Practices Act, Chapters 151 through 165, Occupations Code. In addition, the TMB regulates the delegation of certain medical acts associated with the use of lasers and IPLs under the provisions in Chapter 157, Occupations Code. The TMB adopted Section 193.11, Use of Lasers (22 TAC 193.11), establishing rules for the use of laser and IPL devices for ablative and non-ablative treatment by physicians. Laser hair removal is classified as a non-ablative procedure. The TMB rule requires that the use of laser and IPL devices for non-ablative procedures cannot be delegated to non-physician delegates, other than an advanced heath practitioner, without the delegating/supervising physician being on-site and immediately available. TMB Rule Sec. 193.11 became effective in November 2003. The rule stated that enforcement would begin 12 months after the effective date, or December 2004, to allow adequate time for all persons affected by the rule requirements to come into compliance.

Prior to the effective date of TMB Rule Sec. 193.11, TMB was named as the defendant in two lawsuits challenging this rule in Travis County District Court. Plaintiffs dropped one of these lawsuits and continued with one. *Laser Hair Removal Stakeholders Group v. Texas State Board of Medical Examiners, and Donald W. Patrick, M.D., Executive Director*, Cause No. GN403910 (the Laser Stakeholders Case), which was filed on December 1, 2004, is pending.

Training Requirements

For the reasons discussed in preceding sections, lasers used for hair removal are restricted to use on the order of a specified practitioner within the scope of his/her license. Because of the education required of the professions designated as practitioners by the Section 483.001(12), Health and Safety Code, DSHS believes that the practitioner has received the training necessary to properly use or supervise the use of the device. Training may be conducted during the course of a formal education program and/or an internship, in a training course approved by the licensing body, or by the training division of a manufacturer or distributor.

Other Jurisdictions:

States: The table in Attachment A was compiled by DSHS in January, 2008, using the most current information available from each state. Most states require varying levels of supervision by a physician. Some states require the physician to be on-site and some require the physician to be able to reach the site within a certain timeframe. Some states do not specify the level of physician supervision. A few states allow only physicians to perform the procedures, and a few do not require a physician at all.

- **Conference of Radiation Control Program Directors (CRCPD):** CRCPD is a nonprofit, non-governmental, professional organization of individuals who regulate and control the use of radioactive material and radiation sources. The organization's primary membership is comprised of radiation professionals in state and local government who regulate the use of radiation sources. CRCPD's four major objectives are to: promote consistent radiation protection practices, provide leadership in radiation issues, improve efficiency in providing radiation protection, and enhance relationships between member organizations. CRCPD's Internet site may be accessed at www.crcpd.org. Through membership workgroups, the organization develops suggested state regulations (SSRCR). These SSRCR may be used, in full or in part, by radiation control programs as templates in creating regulations for their use. A SSRCR has been developed for the regulation of lasers, and may be found at: http://www.crcpd.org/SSRCRs/Vol%20II/CONTENTS%20Vol%202.pdf . The DSHS laser regulations found in 25 TAC Chapter 289, which implement the provisions of Chapter 401 of the Texas Health and Safety Code, are based on the CRCPD model.

Stakeholder Comments:

A request for comment on this paper was sent to groups who have regulatory authority over the use of lasers, as well as groups who demonstrated an interest during previous legislative sessions. Only three stakeholders submitted comments: the Texas Dermatological Society, the Laser Training Institute of the Professional Medical Education Association and the Texas Association for Cosmetic Laser Education & Regulation (TACLER).

Comment: Two stakeholder groups commented that the FDA regulations do not use the word "medical" in the definition of a "device" and it should, therefore, be removed from this report.

Response: While the definition of the term "device" does not explicitly contain the word "medical," the terms "device" and "medical device" are used interchangeably under the state and federal regulatory schemes to mean products that have a medical purpose, such as products intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.

Comment: One commenter indicated that hair removal lasers cannot excise, ablate, or vaporize tissue and, therefore, that language should be removed from footnote #1 of the report.

Response: Lasers and IPLs indicated for stable long-term or permanent hair reduction have been approved by FDA for use in performing general and plastic surgery and other dermatological procedures in addition to hair removal. Many of these procedures involve excision, ablation or vaporization of tissues.

Comment: A commenter stated that specific uses of lasers from hair removal devices noted in footnote #1 (i.e., tattoo removal, treatment of pigmented and vascular lesions) are not general uses of these devices and the language should be removed.

Response: Lasers and IPLs indicated for stable long-term or permanent hair reduction have been approved by FDA for use in performing general and plastic surgery and other dermatological procedures in addition to hair removal. 1

Comment: A training requirement outline was submitted by one stakeholder. Those requirements include minimum requirements for certification for all individuals performing laser hair removal procedures in Texas. The suggested requirements are:

A *Laser Hair Removal Practitioner* must be certified by a recognized certifying agency approved by DSHS and meet the requirements for a senior laser hair removal technician certificate.

A *Senior Laser Hair Removal Technician* shall have supervised at least 100 laser hair removal procedures audited by a laser hair removal practitioner and meet the requirements for a laser hair removal technician.

A *Laser Hair Removal Technician* shall have performed at least 100 laser hair removal procedures directly under the supervision of a senior laser hair removal technician or laser hair removal practitioner and meet the requirements of a laser hair removal apprentice-in-training.

A *Laser Hair Removal Apprentice-In-Training* must have at least 24 hours of training in safety, laser physics, skin typing, skin reactions, treatment protocols, and post-

treatment protocols. A laser hair removal apprentice-in-training must work directly under the supervision of a senior laser hair removal technician or laser hair removal practitioner.

The commenter suggested that DSHS recognize, prepare, or administer continuing education programs for all of the above-listed certificate holders. The certificate holders must participate in the continuing education programs as required by DSHS rules.

Response: The creation of the professions in this proposal is dependent on whether the Legislature adopts legislation along the lines discussed in this document, and, if so, the details included in it. Whatever the specifics of that legislation, however, it must contain the federal requirements regarding practitioners and medical devices because the federal requirements are pre-emptive

Comment: Another commenter supplied information on the number of hours of training required in the cosmetic field. Included were: cosmetologist, 1500 hours; esthetician, 600 hours; nail technician 600 hours.

Response: These comments have been noted. The charge for this report focused on current training requirements and regulatory status of laser hair removal. When future training requirements and regulation are contemplated, this information will be considered.

Comment: One comment suggested that the public's use of non-physician supervised treatments indicates that there is not a public out-cry for limiting laser hair removal to physicians or to those supervised/delegated by physicians to perform the procedures.

Response: The use of lasers and IPLs in Texas to achieve stable long-term or permanent hair removal requires physician supervision. Historically, complaints received by DSHS regarding inadequate supervision at these facilities have generally been filed by dissatisfied consumers.

Comment: A stakeholder made the following statements: "a laser produces the same results as a scalpel;" "a laser can be used for procedures other than hair removal;" "electrolysis destroys the hair follicle, a laser destroys cells;" and "an electrolysis machine can only be used for hair removal."

Response: Comments noted.

Comment: The following was provided by the Texas Association for Cosmetic Laser Education and Regulation (TACLER) to support changes to the current regulatory situation for laser hair removal in Texas:

> TACLER supports the certification of all non-health professionals performing laser hair removal as well as the requirement that all laser hair removal facilities be licensed by DSHS. TACLER also supports the

> requirement that each laser hair removal facility shall have a certified laser hair removal practitioner or a licensed health professional meeting the requirements set forth by DSHS present to supervise all laser hair removal procedures performed at the facility during the facility's operating hours.
>
> TACLER also supports the inclusion of a certified laser hair removal practitioner in the definition of "practitioner" among the individuals that may use a prescription device.
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> TACLER supports the requirement that each laser hair removal facility must employ or contract with a consulting physician to establish proper protocols for the services provided at the facility and to audit the laser hair removal facility's protocols and operations. The relationship with the consulting physician must be documented with DSHS.

Response: Comment noted. The charge for this report focused on current training requirements and regulatory status of laser hair removal. When future training requirements and regulation are contemplated, this information will be considered.

Comment: The following comment was provided by a representative of the Texas Professional Medical Education Association to support changes to the current regulatory situation for laser hair removal in Texas:

> I would encourage the State to lead legislation by allowing non-physicians to use lasers & IPL for hair removal and even some other simple tasks like skin rejuvenation or tattoo removal. If the State does require it to be performed by physicians then I would encourage you to enforce that and require that they receive the proper training. My experience overall is that, except for dermatologists and plastic surgeons, that physicians don't really know how to do this safely themselves and simply delegate it out to employees who take it upon themselves to learn properly (if they are credible).

Response: Comment noted. The charge for this report focused on current training requirements and regulatory status of laser hair removal. When future training requirements and regulation are contemplated, this information will be considered.

Comment: One stakeholder included digital photographs of injuries resulting from non-physician use of lasers. Also included was information from a news report (*Medical Spa Nightmares* (3-7-07—Good Morning America) that stated "46% of dermatologists have seen an increase in complication from laser hair removal."

Response: The photographs and video have not been included in the report due to the size of the files. DSHS will make the photos available upon request and will request the video for interested parties upon request.

Comment: A commenter provided a listing of physician groups that had opposed non-physician delegation of hair removal services legislation in the past.

Response: Comment noted.

Comment: The Texas Dermatological Society provided a copy of their recommendations submitted for the 2006 House Public Health Committee Interim Study-Laser Hair Removal.

Response: This document has not been included in the report, but is available upon request from DSHS.

[1] **Pre-market Clearance:** Manufacturers of lasers and IPL devices must comply with the premarket clearance requirements for any device introduced into commerce after the Medical Device Amendments of 1976. Premarket clearance can be obtained either through the premarket notification process under Section 510(k) of the Federal Act or through the premarket approval process under Section 515 of the Federal Act. Lasers and IPLs indicated for stable long-term or permanent hair reduction, including treatment of pseudofolliculitis barbae (PFB), generally have followed the premarket notification process for obtaining premarket clearance from FDA. These lasers and IPLs usually consist of a control console unit and display, power supply, cooling system, footswitch, and one or more handpieces necessary to alter the performance characteristics of the device (i.e. wavelength, pulse frequency, power density and spot size). Manufacturers desiring to obtain clearance using the premarket notification process are required to submit data to the FDA in order to confirm their device is substantially equivalent to other lasers and IPLs currently on the market. Lasers and IPLs used for hair removal are typically granted marketing clearance for a variety of other dermatological and plastic surgery uses, including incision, excision, ablation and vaporization of soft tissue. Specific approved uses include the removal of tattoos and the treatment of pigmented lesions (e.g., dyschromia, hyperpigmentation, lentigos, commonly known as age spots, and keratoses) and vascular lesions (e.g., rosacea, port wine stains, hemangiomas, spider angiomas, leg veins and venous malformations). All known approved premarket notification submissions involving lasers and IPL devices indicated for stable long-term or permanent hair reduction have included a determination by the FDA that the laser or IPL is a prescription device.

[2] **Clinical Investigation:** Lasers and IPL devices used on human subjects for any intended use are required to have met the premarket clearance requirements under the Federal Act or have qualified for an exemption under Section 520(g) of the Federal Act. An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a premarket approval or notification application. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated. Clinical evaluation of devices that have not been cleared for marketing requires:

- an IDE approved by an institutional review board. (If the study involves a significant risk device, the IDE must also be approved by FDA);
- informed consent from all patients;
- labeling for investigational use only;
- monitoring of the study; and
- required records and reports.

An approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements of the Federal Act that would apply to devices in commercial distribution.

[3] **Medical Device Reporting:** The Medical Device Reporting (MDR) regulations adopted in 21 CFR Part 803 provide a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices. User facilities that operate lasers and IPL devices to achieve stable long-term or permanent hair reduction must report to the manufacturer of the device and to the FDA when the user facility becomes aware of information that suggests that one of its devices has or may have caused or contributed to the death of a patient. In addition, if the user facility becomes aware of information that suggests that one of its devices has or may have caused or contributed to the serious injury to a patient, the user facility must report the adverse event to the manufacturer of the device or if the manufacturer is unknown, to the FDA.