

August 15, 2012
Hand Delivery

Department of Public Health
Attn: Jennifer L. Filippone, Chief
Practitioner Licensing and Investigations Section
410 Capitol Avenue, MS#12MQA
P.O. Box 340308
Hartford, CT 06134

Re: Scope of Practice Request
Connecticut State Electrologists Association

Dear Jennifer,

Please find enclosed a Scope of Practice Request on behalf of the Connecticut State Electrology Association to enable electrologists to utilize laser and light based medical devices for epilation in their practices. This is a revised version of the scope of practice request submitted in 2011, but which, sensitive to criticisms contained in the Commissioner 2/1/2012 Report, provides a clearance and off premises supervisory role for physicians. It is believed this will identify patients who are not candidates for laser or light based epilation, who require special precautions or whose treatment should be limited, restricted or directly supervised by a physician. By establishing a mandatory relationship with a physician, post treatment medical attention, if needed, will be facilitated for the patient. We believe this revised request has real merit; addresses many of the concerns raised by the 2/1/2012 report; and is in the public interest. We very much hope you can afford us a review committee slot this year.

Should you have any questions concerning the enclosed please do not hesitate to contact me at (860) 678-1972 or our lobbyist, David J.D. Evans, Esq. at (860) 522-3343. Thank you in advance for your attention to this request.

Very truly yours,



Donna Crump
Director of Laser Initiative
CSEA

DC/
Encls. as above
cc. Mrs. Karen Kolenda, President CSEA
David Evans, Esq.

Scope of Practice Expansion Request

(Revised 8/14/2012)

submitted by the

Connecticut State Electrology Association

PROPOSAL

CSEA proposes the Connecticut Legislature enact a law that would add the following subsection to Connecticut General Statutes Section 20-9(b):

“...(22) an electrologist in good standing who has been licensed for at least three (3) years and who has successfully completed a supplemental course of study approved by the Department of Public Health in laser hair removal, and who, after having been examined, has been certified as a Certified Medical Electrologist (CME) by the International Commission for Hair Removal Certification (ICHRC) the accrediting body of The Society for Clinical and Medical Hair Removal, Inc. (SCMHR)¹ (or such other certification and certifying authority as the Commissioner may designate) who is removing superfluous body and facial hair (but excluding hair in mucosal areas, eye lashes or brows, or areas within 30 mm of the eye, or from other areas of the face or body where removal by electrolysis would not be indicated) through the use of a laser and/or light-based device(s) cleared by the U.S. Food & Drug Administration for hair removal or reduction upon which he or she has received adequate training, who is acting upon, and within the scope of, the written order of a physician. Said exemption shall be further conditioned upon the maintenance by any such electrologist of professional liability insurance or other indemnity against claims for injury or death for professional malpractice in an amount not less than two hundred fifty thousand (\$250,000.00) dollars for one person, per occurrence, with an aggregate of not less than five hundred thousand (\$500,000.00) dollars. Said exemption shall be further conditioned upon observance by said electrologist of any rules and regulations that may be promulgated by the Commissioner of the Department of Public Health regarding a licensed electrologist’s use of laser or light based medical devices for hair removal.”

This would effectively restore to certain Connecticut licensed electrologists the ability to utilize laser and light based medical devices for hair removal in their practice by exempting them from the operation of the Declaratory Ruling of the Connecticut Medical Examining Board in 1997 defining laser hair removal as the practice of medicine.²

¹See <http://scmhr.org/clinicians/>. This certification meets the requirements of the State of Florida for electrologists wishing to perform laser and light-based hair removal services: see http://www.doh.state.fl.us/mqa/electrolysis/eo_hair-removal.html It also meets the requirements of the State of Texas for certification as a “Laser Hair Removal Technician.” See <http://www.dshs.state.tx.us/radiation/laserhair.shtm#Reg>.

² Ratzan, Richard M. “In Re: Petition Submitted by Theresa Petricca... Declaratory Ruling,” http://www.ct.gov/dph/lib/dph/phho/medical_board/declaratory_rulings/declaratoryrulinglaserhairremoval.pdf, (1998)

ELECTROLOGY

Electrology is the practice of permanent hair removal through the use of electrical current or radio waves. Galvanic electrolysis was first reported in the medical literature in 1875. The practitioner inserts a solid, hair-thin metal probe (negative electrode or anode) into the hair follicle while the patient holds a connected wire encased in a wet pad (positive electrode or cathode) which delivers electrical current to the follicle which is then damaged when sodium hydroxide (lye) is produced (known as the galvanic method). Electrothermolysis uses alternating current or shortwave radio waves transmitted into the hair follicle again by a needle or hair-thin metal probe to produce a short pulse of thermal energy to achieve follicular destruction. A simultaneous combination of both modalities is sometimes used by the practitioner and is called "blend."^{3 4} The hair shaft is then removed easily with a forceps. The probe itself is attached through wires to a medical device regulated by the F.D.A. called an "epilator" from which high frequency radio waves or electrical current is produced and controlled. The operator must, among other things, adjust settings for strength, duration and type of current or frequency. By 1951, electrology was established in Connecticut as an allied health profession supervised by the Department of Health. (In Connecticut the profession was called "Hypertrichology," Greek for the science of the study of excessive or unwanted hair growth, until 2001 when P.A. 01-109 changed "hypertrichology" to "electrology," as it is now known.)

In Connecticut electrology is regulated as a profession under a five-member Board of Examiners of Hypertrichologists (the Board's name was never changed) which advises the Commissioner of the Department of Public Health on matters pertaining to the profession, and with the consent of the Commissioner, establishes minimum requirements for certification. This Board by statute consists of a dermatologist, two electrologists, and two lay persons. The board hears and decides matters concerning suspension or revocation of licensure, adjudicates complaints against practitioners, and imposes sanctions where appropriate. The causes for which a license may be revoked or suspended, or for which a practitioner may be the subject of disciplinary action, include (1) Conviction, either within or without this state, of any crime in the practice of the practitioner's profession; (2) fraudulent or deceptive conduct in the course of professional services or activities or illegal, incompetent or negligent conduct, in the practitioner's practice; (3) habitual intemperance in the use of alcoholic liquor or addiction to the use of narcotics or other habit-forming drugs; (4) violation of any provision of this chapter or of any regulation adopted under this chapter; (5) aiding or abetting the unlawful practice of electrology; (6) physical or mental illness or emotional disorder or loss of motor skill of the practitioner, including, but not limited to, deterioration through the aging process; (7) fraud or material deception in obtaining a license; or (8) splitting of fees or offering of commissions or gifts. The Commissioner of Public Health may order a licensee to submit to a reasonable physical or mental examination if the physical or mental capacity of the licensee to

³ "Electrology," *Wikipedia, the Free Encyclopedia*. <http://en.wikipedia.org/wiki/Electrology> (Accessed 13 August 2012).

⁴ Sen, Priya. "Unwanted Hair Removal –An Update," *Institute of Dermatology, Singapore Dermatology Bulletin* 20 (2009): 6-8. <http://www.nsc.gov.sg/doc/fckeditor/pdf/Derm%20Bulletin%20Vol%2020%20No%202%202009.pdf#page=6>

practice safely is the subject of an investigation. The commissioner may petition the superior court for the judicial district of Hartford to enforce such order.⁵

Candidates for admission to the profession must have a high school diploma and have successfully completed a professional education program which consists of a minimum of at least 200 hours of classroom instruction in basic sciences applicable to electrology, including but not limited to bacteriology, sanitation and hygiene, biology, dermatology, trichology, theory of electricity, electrolysis, and principles of infection control; and they must have had at least 400 hours of practical instruction in epilation techniques, utilizing electrolysis (direct current/DC), and thermolysis (alternating current/AC) modalities. Each such professional education program must be approved by the Board of Examiners and receive the consent of the Department of Public Health. For initial licensure the passing of a written and practical examination is necessary.⁶

Electrologists must complete a minimum of 10 contact hours of qualifying continuing education per annum, at least two of which must be in infection control, blood-borne diseases, universal precautions or sanitation and sterilization, or any combination thereof.⁷ Cardiopulmonary resuscitation training is routinely provided and encouraged as a continuing education choice in CSEA organized continuing education programs.

Electrologists observe FDA-approved Infection Control Standards.⁸

Electrologists are regulated as a profession in Rhode Island,⁹ New Hampshire,¹⁰ Maine,¹¹ Massachusetts,¹² and Vermont¹³ within New England, as well as in nearby New Jersey.¹⁴ New York has chosen not to regulate electrolysis in any way.^{15 16}

⁵ *General Statutes of Connecticut*, Title 20 § 267. <http://www.cga.ct.gov/2011/pub/Chap388.htm#Sec20-267.htm>

⁶ *Regulations of the Connecticut Department of Public Health*, Title 20 § 271 *et seq.*
http://www.ct.gov/dph/lib/dph/agency_regulations/dph_regulations-9.1.2009

⁷ *Regulations of the Connecticut Department of Public Health*, Title 20 § 275b-.
http://www.ct.gov/dph/lib/dph/agency_regulations/dph_regulations-9.1.2009.pdf

⁸ See "Infection Control Standards for the Practice of Electrology," American Electrology Association: 1988.
http://www.fda.gov/ohrms/dockets/ac/02/briefing/3839b1_18_aea.doc

⁹ *State of Rhode Island General Laws*, Title 5 § 32.
<http://www.rilin.state.ri.us/Statutes/TITLE5/5-32/INDEX.HTM>

¹⁰ *New Hampshire Statutes*, Title 30 § 314.
<http://www.dhhs.nh.gov/oos/bic/electrologist/documents/electrologistlaws.pdf>

¹¹ *Maine Revised Statutes*, Title 32 § 18. <http://www.mainelegislature.org/legis/statutes/32/title32ch18sec0.html>

¹² *Massachusetts General Laws*, Title 16 § 112-87FFF.
<http://www.malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section87FFF>

¹³ *Vermont Statutes*, Title 26 § 86-4402.
<http://www.leg.state.vt.us/statutes/fullsection.cfm?Title=26&Chapter=086&Section=04402>

¹⁴ *New Jersey Permanent Statutes*, Title 45 § 9. <http://www.njleg.state.nj.us/>

¹⁵ *People v. Marcus*, 538 N.Y.S. 2d 928 (1989).

¹⁶ "Consumer Guide to Beauty Salons & Spas," New York Dept. of State.
http://www.dos.ny.gov/licensing/pdfs/beauty_salon_guide.pdf

LASER HAIR REMOVAL

LASER¹⁷ technology was invented in the late 1950s. Lasers are devices that emit a focused and amplified beam of light (electromagnetic radiation). As the technology has advanced numerous commercial applications for them have developed and experimentation was undertaken to find a technique to permit them to be harnessed for hair removal. In 1997,¹⁸ the technology became sufficiently advanced to permit the FDA to clear to market the first machines approved for removal of body hair in bulk through selective photothermolysis.^{19 20} (Electrology is based on the theory of selective thermolysis.) The low energy beam of light is selectively absorbed by the melanin within the hair shaft and follicle acting as a chromophore, causing their coagulation and destruction by heat while the surrounding epidermal tissue remains largely unaffected.^{21 22} The advantage of the typical laser hair removal device over the most advanced needle-type electrolysis epilators is that an operator has the ability to treat a large area of skin at one appointment, making laser hair removal cost-effective and faster than tweezing, waxing, or electrolysis. (In electrolysis, a metallic probe is inserted under magnification into the hair follicles to be treated; a pulse of current or radio waves is then directed into the follicle after which the hair shaft is removed with forceps.) With laser, a dime or larger width's beam of light emitted from a hand-piece (similar in size, weight and shape to the hand scanners used by cashiers in retail establishments) is passed over the area of skin where hair removal is desired. The area to be treated is shaved by the patient prior to arrival. According to experts, a given area of a client's body may be treated up to 50 or even 60 times faster with the laser hand-piece than with a traditional electrolysis needle or probe.^{23 24} According to studies by physicians, their patients prefer laser hair removal favorably to electrolysis because of its

¹⁷ An acronym for "Light Amplification by Stimulated Emission of Radiation."

¹⁸ Hobbs, L. "Synopsis of Laser Assisted Hair Removal Systems." *Skin Therapy Letter* 5 (2000).

http://www.skintherapyletter.ca/stl/download/stl_5_3.pdf

¹⁹ Sahoo, Alison. *A Brief History of Laser Hair Removal Technology*. Palomar Industries, 1997.

²⁰ For a brief explanation of the history of the invention of selective photothermolysis and the technical operation of a laser see *Mehl/Biophile International Corp., et al v. Milgraum* 8 F. Supp 2d (D.NJ.1998):434-5.

http://scholar.google.com/scholar_case?case=8641386165244690622&q=electrolysis+permanent+hair+removal&hl=en&as_sdt=2,7

²¹ Dierickx, Christine C. *Laser Hair Removal: Scientific Principles and Practical Aspects*. Lumenis, Inc., 2002.

http://www.aesthetic.lumenis.com/pdf/laser_principles_aspects.pdf

²² "Laser Hair Removal," *American Academy of Dermatology (website)*.

<http://www.aad.org/media-resources/stats-and-facts/cosmetic-treatments/laser-hair-removal>

²³ Sahoo, Alison. *A Brief History of Laser Hair Removal Technology*. Palomar Industries, 1997.

²⁴ "Laser Hair Removal," *Wikipedia, the Free Encyclopedia*. http://en.wikipedia.org/wiki/Laser_Hair_Removal (Accessed 13 August 2012).

speed and relative painlessness.^{25 26} The American academy of Dermatology states on its website that dermatologists use lasers and light sources to safely and effectively treat larger areas of unwanted hair with minimal patient discomfort and fewer complications than other hair-reduction methods.²⁷ Alicia Zalka, M.D., a Connecticut dermatologist's website proclaims: "[lasers] offer better long-term results and fewer side effects than all of the other methods."²⁸ As an example, to remove the unwanted hair from a person's back by traditional electrolysis might take 10-30 hours (depending on the number of visible hair shafts on the area to be treated) typically requiring multiple visits, while the same clearance might be achieved with a laser in a single 30 minute session.^{29 30} In either case, subsequent maintenance treatments would be needed with the time disparities on a similar order of magnitude.

THE DECLARATORY RULING OF 1997 – ITS PROBLEMS AND UNINTENDED CONSEQUENCES

The electrology profession has been divided or ambivalent about the use by electrologists of laser hair removal devices since their commercial introduction. When first introduced in 1997 they were intimidating, expensive and relatively unproven in their efficacy, particularly on fair-haired or darker-skinned clients. Due to the inexperience and lack of training of operators, both licensed and unlicensed, medical or non-medical, (as in many states no training whatsoever was needed to procure and operate lasers) there were side effects and injuries. These were primarily skin burns due to use of improper settings or failure to conduct skin patch tests (primarily on tanned or darker skinned subjects) and eye injuries (though rarely disabling), usually to operators when the lasers were fired ignorantly into or near eyes.^{31 32 33} Electrology's chief competitors in the pre-laser era were depilatories, waxing, and tweezing. The profession built itself around the assertion that the

²⁵ Preston, PW and Lanigan, SW. "Patient Satisfaction with Laser Hair Removal." *Journal of Cosmetic Dermatology* 2, no. 2 (2003): 68-72. See <http://www.ncbi.nlm.nih.gov/pubmed/17156059> for abstract.

²⁶ Haedersdal, H. and Haak, C.S. "Hair Removal." *Current Problems in Dermatology* 42, (2011):111-21. See <http://www.ncbi.nlm.nih.gov/pubmed/21865803> for abstract.

²⁷ "Laser Hair Removal," *American Academy of Dermatology (website)*. <http://www.aad.org/media-resources/stats-and-facts/cosmetic-treatments/laser-hair-removal>

²⁸ "Laser Hair Removal," *Dermatology Associates of Western Connecticut, PC (website)*.

http://www.dermwestconn.com/descriptions/laser_hair_desc.html

²⁹ Dierickx, Christine C. *Laser Hair Removal: Scientific Principles and Practical Aspects*. Lumenis, Inc., 2002. http://www.aesthetic.lumenis.com/pdf/laser_principles_aspects.pdf

³⁰ "Laser Hair Removal," *American Academy of Dermatology (website)*. <http://www.aad.org/media-resources/stats-and-facts/cosmetic-treatments/laser-hair-removal>

³¹ "Laser Accident Database," *Rockwell Laser Industries (website)*.

<http://www.rli.com/resources/accident.aspx>; also see "MAUDE- Manufacturer and User Facility Device Experience," *US Food and Drug Administration (website)*. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>

³² "MAUDE- Manufacturer and User Facility Device Experience," *US Food and Drug Administration (website)*. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>

³³ "Laser Hair Removal: Safety Guidelines for Facility Owners & Operators," *British Columbia Centre for Disease Control: 2005*. <http://www.bccdc.ca/NR/rdonlyres/8DD1B6DD-5FBB-4C74-86D3-8853A3CE553B/0/LaserHairRemovalGuidelinesWorkersfinal.pdf>

various electrolysis modalities provided “permanent hair removal,” a claim the FDA supports.³⁴ The FDA definition of “permanent hair removal,” however, is a 30% decrease in hair re-growth three months after a single treatment.³⁵ As the use of lasers for hair removal commenced, the American Electrology Association³⁶ chose to take the position that employment of such devices by electrologists would be unprofessional as their use had not been shown to result in “permanent hair removal.”³⁷ (The FDA’s position has been that manufacturers of devices that may be used to remove body/facial hair may not claim that laser hair removal is either painless or permanent unless the FDA determines that there are sufficient data to demonstrate such results. Several manufacturers as of this date have received FDA permission to claim “permanent reduction” for their lasers. According to the FDA, this means that “although laser treatments with these devices will permanently reduce the total number of body hairs, they will not result in a permanent removal of all hair. The specific claim granted is ‘intended to effect stable, long-term, or permanent reduction’ through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing after a treatment regime, which may include several sessions. The number of hairs re-growing must be stable over time greater than the duration of the complete growth cycle of hair follicles, which varies from four to twelve months according to body location. Permanent hair reduction does not necessarily imply the elimination of all hairs in the treatment area.”^{38 39})

In November 1996, the American Electrology Association’s then President, Theresa Petricca, also a Connecticut licensed electrologist, sought a ruling from the Connecticut Board of Medical Examiners that laser hair removal was a medical procedure and thus outside the scope of practice of electrologists. The board accommodated her. The decision did also have the consequence of barring the use by medical spas of non-professional personnel to operate lasers, at least for hair removal purposes. The Board cited among its reasons that: “Laser hair removal is an evolving technology which does not currently provide permanent results. Results vary...”⁴⁰ It is unclear from the record whether any opposition to this request occurred. Neither the Connecticut State Electrology Association nor any of the other 248 other licensed electrologists in the state in 1997 were parties to that proceeding, and virtually all of them learned about it after the fact. In 2004, the AEA modified its position to permit its members to utilize laser hair removal devices in their practice,

³⁴“Frequently Asked Questions About Permanent Hair Removal,” *American Electrology Association, Inc. (website)*.

<http://www.electrology.com/consumer/faq.html>

³⁵ Sarkar, P. “Update on Laser hair Removal.” *Cosmetic Dermatology* 20, no. 7 (2007).

<http://www.cosderm.com/PDF/020070440.pdf>

³⁶ The American Electrology Association (AEA), established in 1958, is the largest international nonprofit membership organization for permanent hair removal professionals. See <http://www.electrology.com/aboutus.html>

³⁷“Laser Facts,” *US Food and Drug Administration (website)*. [http://www.fda.gov/Radiation-](http://www.fda.gov/Radiation-EmittingProducts/ResourcesforYouRadiationEmittingProducts/ucm252761.htm)

[EmittingProducts/ResourcesforYouRadiationEmittingProducts/ucm252761.htm](http://www.fda.gov/Radiation-EmittingProducts/ResourcesforYouRadiationEmittingProducts/ucm252761.htm)

Also, see *Removatron International Corporation et al vs. FTC*, 884 F.2d 1489 (1st Cir. 1989).

http://scholar.google.com/scholar_case?case=14571436479757407627&q=electrolysis+permanent+hair+removal&hl=en&as_sdt=2,7

³⁸ “Laser Facts,” *US Food and Drug Administration (website)*.

<http://www.fda.gov/Radiation-EmittingProducts/ResourcesforYouRadiationEmittingProducts/ucm252761.htm>

³⁹ *Removatron International Corporation et al vs. FTC*, 884 F.2d 1489 (1st Cir. 1989).

http://scholar.google.com/scholar_case?case=14571436479757407627&q=electrolysis+permanent+hair+removal&hl=en&as_sdt=2,7

⁴⁰ Richard M. Ratzan, “In Re: Petition Submitted by Theresa Petricca... Declaratory Ruling,”

http://www.ct.gov/dph/lib/dph/phho/medical_board/declaratory_rulings/declaratoryrulinglaserhairremoval.pdf, (1998).

provided they concurrently offered traditional electrolysis services.⁴¹ In the 15 years that have elapsed since the CBME Declaratory Ruling, the number of licensed electrologists in Connecticut has fallen successively every year and now is hovering at 166. Those still practicing have seen their client loads diminish. This state of affairs is hardly limited to Connecticut. The Electrologists Association of California's January 2011 Newsletter entitled "The Future of Electrology?," in which the future of the profession is forecast by many of its foremost practitioners, is replete with gloom.⁴²

Although electrolysis currently remains the preferred method of hair removal for certain areas of the body (eyebrows), or on clients with certain hair colors (strawberry or blonde), or people with certain medical or dermatologic conditions that contraindicate laser in its present degree of evolution (immune deficiencies), or to "clean up" areas after the final courses of laser treatment, electrolysis's role in the hair removal industry seems to be in eclipse.

EVOLUTION OF LASER HAIR REMOVAL SINCE 1997

Since 1997, major advances in laser hair removal technology and procedures have occurred.⁴³ These include the addition of better filters, cooling systems to chill the non-targeted skin (contact, cryogen spray or air, now mandatory for FDA device approval), the development of lasers that are effective on darker-skinned subjects, the development of better lasers for epilation (the long-pulsed diode laser), refinement in choice of equipment, pulse and fluence in conjunction with use of the Fitzpatrick Skin scale and patch testing to improve candidate selection, and choice of laser.^{44 45}

A meta-analysis of all published studies done during the period 1997-2003 by A. Sadighha et al found that hair reduction at least 6 months after the last treatment were 57.5, 42.3, 54.7, and 52.8% after three sessions for diode, Nd:YAG, alexandrite, and ruby lasers, respectively.⁴⁶

In a study of 210 patients who underwent hair removal by IPL, a mean hair reduction of 80% was reported after 3-5 treatments.⁴⁷

⁴¹ Per Donna M. Crump, CLE, AEA member and past president of the CSEA.

⁴² "The Future of Electrology?" *Electrologists Association of California* 25, no. 3 (2011).

<http://www.electrolca.accountsupport.com/EACJan2011newsletter.pdf>

⁴³ "Plastic Surgery for Laser Hair Removal Treatment and Management," *Medscape Reference (website)*.

<http://emedicine.medscape.com/article/1271154-treatment#aw2aab6b3b2>

⁴⁴ Haedersdal, M. and Gotzsche, P. "Laser and Photoepilation for Unwanted Hair Growth." Cochrane Skin Group, 2006. The Cochrane online database is available at <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004684.pub2/full>

⁴⁵ "Plastic Surgery for Laser Hair Removal Treatment and Management," *Medscape Reference (website)*.

<http://emedicine.medscape.com/article/1271154-treatment#aw2aab6b3b2>

⁴⁶ Sadighha, A. and Mohaghegh Zahed, G. "Meta-Analysis of Hair Removal Laser Trials." *Lasers Med Sci* 24, no. 1 (2009): 21-5. <http://www.ncbi.nlm.nih.gov/pubmed/18027066>

⁴⁷ "Plastic Surgery for Laser Hair Removal Treatment and Management," *Medscape Reference (website)*.

<http://emedicine.medscape.com/article/1271154-treatment#aw2aab6b3b2>

In a study of 2,359 subjects conducted in Istanbul over the period September 2005 through May 2008 with a long-pulsed alexandrite laser, it was reported that at six months after the last of multiple treatments, the subjects experienced a mean 80.6% hair reduction. Complications occurred in only 2.2% of cases, including transient hyperpigmentation (0.7%), folliculitis (0.5%), transient hypopigmentation (0.5%), and blistering (0.4%). No subjects had scarring or long-term pigmentary changes.⁴⁸

In a recently completed study presented in April 2010 to the 30th annual conference of the American Society of Laser Medicine & Surgery consisting of 2,448 subjects treated in Rio de Janeiro using a diode laser with low fluence, 6 months after 6 treatment sessions spaced 4-6 weeks apart, 90% of subjects reported an excellent result with the remaining 10% reporting a good result, all without any complications.⁴⁹

Melanie Grossman, M.D., a Clinical Instructor in Dermatology at Columbia Presbyterian Medical Center, claims that her clients experience 80% permanent hair reduction in 4-7 treatments.⁵⁰

Christine Dierickx, M.D., a prominent laser hair removal researcher and Visiting Professor at Wellman Laboratories of Photomedicine at Harvard in a recent study of 100 subjects found that the diode laser produced temporary hair loss in 100% of the subjects and permanent hair reduction in 89% of patients at one year.⁵¹

Merite Haedersdal, M.D. Ph.D., a prominent laser hair removal researcher, Visiting Research Scientist and Professor of Dermatology at Mass. General Hospital, concluded in a meta-study published in 2006 based on a total of 9 randomized controlled and 21 controlled trials that the then-present best available evidence showed that (i) epilation with lasers and light sources induces a partial short-term hair reduction up to 6 months postoperatively, (ii) efficacy is improved when repeated treatments are given, (iii) efficacy is superior to conventional treatments (shaving, wax epilation, electrolysis), (iv) evidence exists for a partial long-term hair removal efficacy beyond 6 months postoperatively after repetitive treatments with alexandrite and diode lasers, and probably after treatment with ruby and Nd:YAG lasers, whereas evidence is lacking for long-term hair removal after IPL treatment, (v) today there is no evidence for a complete and persistent hair removal efficacy, (vi) the occurrence of postoperative side-effects is reported low for all the laser systems.⁵²

These are just a handful of the studies that have been reported on the results of use of lasers in hair removal since 1997. According to the FDA the popularity of laser hair removal has increasingly grown, prompting many laser manufacturers to conduct research and seek FDA clearance for their lasers for this indication. The market is growing so quickly that FDA cannot

⁴⁸ Kutlubay, Z. "Alexandrite Laser Hair Removal Results in 2359 Patients: A Turkish Experience." *Journal of Cosmetic Laser Therapy* 11, no. 2 (2009): 85-93. <http://www.ncbi.nlm.nih.gov/pubmed/19466642>

⁴⁹ American Society of Laser Medicine and Surgery 30th Annual Conference (2010).

⁵⁰ Grossman, Melanie. See <http://www.hairremovaljournal.org/does.aspx>

⁵¹ Dierickx, Christine C. *Laser Hair Removal: Scientific Principles and Practical Aspects*. Lumenis, Inc., 2002.

http://www.aesthetic.lumenis.com/pdf/laser_principles_aspects.pdf

⁵² Haedersdal, M. "Evidence-Based Review of Hair Removal Using Lasers and Light Sources." *Journal of the European Academy of Dermatology and Venereology* 20, no. 1 (2006): 9-20. <http://www.ncbi.nlm.nih.gov/pubmed/16405602>

maintain an up-to-date list of all laser manufacturers whose devices have been cleared for hair removal, as this list continues to change.⁵³

THE LASER HAIR REMOVAL MARKET

According to the Millennium Research Group, one of the largest American medical research marketing organizations, in the U.S., laser hair removal is the fastest-growing **non-surgical** aesthetic laser application. They report an estimated 3.1 million laser hair removal procedures to have been performed in 2006, representing a 22% increase over 2005.⁵⁴ According to the American Academy of Plastic Surgery, their members alone self-reported reported 937,682 hair removal procedures in 2010, up from 893,054 in 2009.⁵⁵ The American Society for Aesthetic Plastic Surgery's cosmetic surgery statistics, which are touted to be the most comprehensive collection of data available on the number of cosmetic surgical and nonsurgical procedures performed in the United States, project 936,270 laser hair removal procedures performed by plastic surgeons, otolaryngologists and dermatologists in 2010.⁵⁶

FEDERAL REGULATION of COSMETIC LASERS and IPLs

Cosmetic lasers and intense pulse light devices currently used for hair removal or reduction are medical devices as defined under Section 201(h) of the Food, Drug and Cosmetic Act.⁵⁷ Manufacturers, distributors, and users of these lasers⁵⁸ and IPLs (intense pulse lights)⁵⁹ must comply with the applicable provisions of the Federal Act. These requirements include (a) complying

⁵³ "Radiation Emitting Products," *US Food and Drug Administration (website)*. <http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/SurgicalandTherapeutic/ucm142607.htm>

⁵⁴ "U.S. Markets for Aesthetic Lasers," Millennium Research Group: 2006.

⁵⁵ American Society of Plastic Surgeons. *2010 Cosmetic Plastic Surgery Statistics*. <http://www.plasticsurgery.org/Documents/news-resources/statistics/2010-statistics/Overall-Trends/2010-cosmetic-plastic-surgery-minimally-invasive-statistics.pdf>

⁵⁶ "Top 5 Procedures: Surgical and Nonsurgical." American Society for Aesthetic Plastic Surgery: 2010. <http://www.surgery.org/sites/default/files/2010-top5.pdf>

⁵⁷ 21U.S.C.321. See <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterslandIIShortTitleandDefinitions/ucm086297.htm> and

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm>

⁵⁸ A cosmetic laser device typically consists of a control console, power supply, cooling system, footswitch and hand-piece.

⁵⁹ See Dr. Li's video on YouTube for a quick but useful video explanation of the operation of an IPL device. <http://www.youtube.com/watch?v=uY13jq-z5oQ>

or salons.^{64 65} Possession of aesthetic lasers is not restricted, and the choice is left to the consumer whether they wish to receive hair removal treatment from a physician, other health professional, such as an R.N. or P.A., or prefer a cosmetologist or electrologist.^{66 67} This is presently the state of affairs within most countries of the European Union.⁶⁸

REGULATION IN THE OTHER 49 STATES GENERALLY

The Texas Department of State Health Services, at the request of its legislature in 2007, studied the regulation of laser hair removal devices in the United States.⁶⁹ As part of its report it prepared an "Attachment A" which is a summary table of the regulatory framework then in place on a state-by-state basis in the United States as of the time of its compilation, January 2008. The Executive Summary and the table referred to as "Attachment A" are available for download at the website of the Texas Department of State Health Services.⁷⁰ Another table prepared for the American Society of Dermatologic Surgery has a similar table which was apparently compiled in February, 2008.⁷¹

A review of these tables discloses wide variation in method of regulation among the several states as well as inconsistencies among the tables themselves.

⁶⁴ "Laser Hair Removal: Safety Guidelines for Facility Owners & Operators," British Columbia Centre for Disease Control: 2005. <http://www.bccdc.ca/NR/rdonlyres/8DD1B6DD-5FBB-4C74-86D3-8853A3CE553B/0/LaserHairRemovalGuidelinesWorkersfinal.pdf>

⁶⁵ "Guidelines for Personal Services Establishments," British Columbia Ministry of Health and Ministry Responsible for Seniors. <http://www.healthservices.gov.bc.ca/protect/pdf/pse.pdf>

⁶⁶ Galt, Virginia. "Laser Hair Removal a Risky Business in Need of Regulation, Experts Say." *Canadian Medical Association Journal* 182 no. 8 (2010). <http://www.cmaj.ca/content/182/8/755.full>

⁶⁷ "Cosmetic Laser Treatments" *Health Canada* (website). http://www.hc-sc.gc.ca/hl-vs/alt_formats/pacrb-dgapcr/pdf/iyh-vsv/med/laser-eng.pdf

⁶⁸ CEN – the European Committee for Standardization has created a new Project Committee, CEN/TC 403 "Project Committee- Aesthetic surgery services," the aim of which is to elaborate European Standards for aesthetic surgery services. The first meeting of that Committee was held in September 2010 and its work remains incomplete.

http://www.ipras.org/sites/default/files/Aesthetic_Surgery.pdf and http://www.iqum-ipras.org/FinalReportIquam2010_website2.pdf

⁶⁹ "Final Report on the Regulation of Laser Hair Removal." Texas Department of State Health Services: 2009. The Executive Summary of the Report and Appendix A are available at the Texas Department of Health Services website, "Publications-Radiation Control Program,"

<http://www.dshs.state.tx.us/Layouts/ContentPage.aspx?PageID=35849&id=4537&terms=Executive+AND+Summary+AND+Laser>

⁷⁰ "Final Report on the Regulation of Laser Hair Removal." Texas Department of State Health Services: 2009. The Executive Summary of the Report and Appendix A are available at the Texas Department of Health Services website, "Publications-Radiation Control Program,"

<http://www.dshs.state.tx.us/Layouts/ContentPage.aspx?PageID=35849&id=4537&terms=Executive+AND+Summary+AND+Laser>

⁷¹ This table may be accessed through the AADS website: <http://www.asds.net/search.aspx?searchtext=electrologists>

with labeling and use restrictions for prescription devices; (b) obtaining pre-market clearance⁶⁰ prior to introducing the device into commerce; (c) adhering to any special controls required as a result of the classification assigned to a device; (d) conducting clinical investigations 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.⁶¹ They are considered “prescription devices” as defined in 21CFR 801.109, and thus may only be sold to a “practitioner licensed by state law to use or order the use of such device(s)” or used by or under the supervision of such a person.⁶² The FDA also sets performance standards for the devices to prevent unnecessary exposure to radiation during use of the products, and they must comply with the requirements set forth in 21CFR 1040.10 et seq. for medical laser products.⁶³

LASER HAIR REMOVAL BEYOND CONNECTICUT

Regulation of who may possess and operate laser hair removal devices currently varies widely throughout the United States, Canada, and the European Union, and like the technology itself, it is evolving, but not in any particular pattern. At present it can only be described as hodgepodge with considerable variation between states on whether use of light-based hair removal devices constitutes the practice of medicine, electrology, cosmetics, or aesthetics, or some of each. In the absence of a well-accepted pre-existing framework, there is wide variation in who may possess and use aesthetic lasers.

CANADA and the EUROPEAN UNION

In Canada, facilities possessing cosmetic lasers are regulated at the provincial level as “Personal Service Establishments” equivalent to our state regulation of health spas and beauty spas

⁶⁰ Manufacturers of lasers and IPL devices must comply with the premarket clearance requirements for any device introduced into commerce. Premarket clearance can be obtained either through the premarket notification process under Section 510(k) of the Act or through the premarket approval process under Section 515 of the Act.

⁶¹ See 21CFR 803. The FDA’s website provides details regarding the method of reporting. See <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>

⁶² 21CFR 801.109 See the FDA’s website, “Device Advice: Comprehensive Regulatory Assistance,”

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>

See also “Final Report on the Regulation of Laser Hair Removal,” Texas Department of State Health Services: 2009. The Executive Summary of the Report and Appendix A are available at “Publications-Radiation Control Program,” *Texas Department of Health Services (website)*.

<http://www.dshs.state.tx.us/Layouts/ContentPage.aspx?PageID=35849&id=4537&terms=Executive+AND+Summary+A+ND+Laser>

⁶³ “Standards (Medical Devices),” *US Food and Drug Administration (website)*.

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

In all states, physicians are permitted to operate the devices. In some states there are no restrictions, either by training or licensure, to whom or under what arrangements they may delegate.

In New York, hair removal is not deemed the “practice of medicine.”⁷²

Many states permit non-physician licensees to operate the devices independently. Although it varies, the permitted licensees include electrologists, cosmeticians and cosmetologists, aestheticians, registered nurses, physician’s assistants, and laser technicians.⁷³ Others permit electrologists or other licensees to operate the devices under various levels of physician supervision. In some instances, the supervising physician must be on the premises exercising direct oversight;⁷⁴ in some, the physician must be immediately available.⁷⁵ In some instances, pre-screening by physicians of patients or clients is required,⁷⁶ while in others, the existence of written treatment protocols suffice.⁷⁷ Most of the states that have recently legislated in this area have granted or confirmed electrologists’ authority to use hair removal lasers.⁷⁸ Some states are now requiring formal training along with or in place of certification for operators.⁷⁹

In several places, there is no positive law that may be readily consulted to determine the nature of regulation, if any.⁸⁰

The CSEA has not been able to review every state’s regulatory arrangements since the publications of the aforementioned Tables. There is circulating among the Laser Hair Removal Scope of Practice Review Committee members a table prepared by the American Academy of Dermatologic Surgery Inc. entitled “Laser Hair Removal Laws by State” with an indication it was revised 9/22/10, to which reference may be had as well. In consulting these tables, it is important to remember that changes have occurred in some states’ regulatory frameworks since they were compiled, as the field of laser hair removal has been in constant flux. Among those states where there have been changes since these tables were compiled are these:

FLORIDA

Florida passed legislation in 2009 that permitted electrologists with supplemental training and certification as a Certified Medical Electrologist (CME) by the International Commission for Hair Removal Certification (ICHRC), the accrediting body of The Society for Clinical and Medical Hair Removal, Inc. (SCMHR), to operate lasers under the general but off-site supervision of a physician.⁸¹

⁷² *People v. Lehrman*, 251 App. Div. 451, 296 N.Y.S. 580 (N.Y. App. Div. 1937). The court rebuffed an attempt by the state to prosecute an electrologist for engaging in the “practice of medicine” without a license.

⁷³ Virginia, Vermont and Tennessee are among the states where electrologists practice laser hair removal independently. For Tennessee, see <http://www.state.tn.us/sos/rules/0540/0540-01.pdf>

⁷⁴ These include Louisiana.

⁷⁵ These include Colorado and Kansas.

⁷⁶ These include Arkansas and Alaska.

⁷⁷ These include Florida and Texas.

⁷⁸ These include North Carolina, Ohio, Illinois, Texas, Vermont and Florida.

⁷⁹ These include North Carolina, Ohio, Texas, Georgia and Florida.

⁸⁰ E.g. The District of Columbia.

⁸¹ Florida Administrative Code, Division 64B8-56. This is reproduced as Appendix A to this submission.

VERMONT

In 2011, Vermont enacted legislation that expanded the definition of electrology to “include[s] the use by properly trained licensed electrologists of lasers approved by the United States Food and Drug Administration for electrology and as otherwise permitted by Vermont law.”⁸²

MASSACHUSETTS

On June 24, 1998, citing the December 17, 1997 decision of the Connecticut Board of Medical Examiners, the Massachusetts Board of Registration in Medicine by a unanimous decision determined that the use of “lasers for hair removal is within the scope of medical practice.” This was followed by the adoption of a passage of legislation that reposed authority to regulate lasers in the Department of Public Health.⁸³ In 2006, a Medical Spa Task Force comprised of members drawn from the Boards of Registration in Cosmetology, Electrology, Nursing, and Medicine, as well as including dermatologists, plastic surgeons, nurses, and consumers,⁸⁴ was established by the Massachusetts legislature to study the issues presented by the advent of aesthetic lasers. Its report was filed on January 12, 2009.⁸⁵ Efforts to implement all the findings of the Task Force legislatively have not as yet been successful. Recommendation 5 of the Task Force was that the Board of Registration in Medicine should amend its definition of laser hair removal as the practice of medicine. “The Board of Registration in Medicine currently defines laser hair removal as the practice of medicine, which should preclude anyone other than physicians and properly supervised nurses from performing such procedures. In recent years, however, laser hair removal has begun to replace traditional electrolysis, and is widely used by electrologists and aestheticians. The Task Force reviewed this matter, and concluded that the use of lasers to remove superfluous hair from the body can be done in a safe and effective manner by licensed professionals other than physicians and nurses, providing those individuals are properly and adequately trained for the procedure. Hair removal does not involve examination, diagnosis or treatment of the skin, and therefore does not hold the potential for a practitioner to miss a diagnosis of a pre-cancerous lesion, for example.”⁸⁶ According to the Massachusetts Board of Registration of Electrologists and the Department of Professional Licensure as set forth in Policy Bulletin Regarding Laser Hair Removal Policy 06-, laser hair removal does not fall within the scope of an electrologist’s license. Accordingly, licensed electrologists who perform laser hair removal services must do so in an area separate and

⁸² *Vermont Statutes*, Title 30 § 329-1. This is reproduced as Appendix B to this submission.

⁸³ *Massachusetts General Laws*, Title 16 § 111-51. This is reproduced as Appendix C to this submission.

⁸⁴ “Report of the Medical Spa Task Force,” *Massachusetts Board of Medical Registration (website)*.

<http://www.mass.gov/eohhs/consumer/physical-health-treatment/physicians/announcements-and-publications.html>

⁸⁵ *Ibid.*

⁸⁶ *Ibid.*, pg. 14

distinct from their electrology treatment room.⁸⁷ According to staff counsel for the Board of Registration in Medicine, laser hair removal is considered to be “the practice of medicine” only if done by a physician or under his or her immediate supervision.⁸⁸

TEXAS

Texas enacted legislation effective in 2010 that requires laser hair removal facilities not operated by a physician to have an off-site contractual supervisory and auditing arrangement with a physician; that only an individual possessing certification from a recognized certifying agency (SCMHR has been approved as such in Texas) as a “laser hair professional” supervise such a clinic and that the actual operator possess certification as “laser technician.”⁸⁹

ILLINOIS

Illinois recently enacted legislation that repealed the statutory prohibition on electrologists using laser technology and authorized physicians to delegate services to licensed electrologists.⁹⁰

Based on the ASDS 2010 compilation, as revised for known errors,⁹¹ it appears that currently some 13 states, including Connecticut, require on-site medical supervision for procedures delegated to electrologists, cosmetologists, aestheticians, or technicians (AL, CT, GA, KY, LA, MI, MS, MT, NH, NJ, NM, OK, UT). Some 13 states require some form of off-site medical supervision (AZ, AK, AS, CO, IN, IA, KS, NC, OH, RI, SC, TX, WI). Some 9 states currently do not permit delegation of laser hair removal to these occupations (CA, ID, MD, MN, NE, ND, OR, SD, WA). In some 9 states, plus the District of Columbia, there is a lack of clarity as to the nature of regulation, if any (AK, DE, DC, HI, ME, NV, MO, PA, WV, WY). In 4 states, electrologists are permitted to practice laser hair removal independently (NY, VA, VT, TN). In one state (MA), there is apparent conflict in the status, as the Board of Registration of Medicine is in open conflict with the Board of Examiners of Electrology.

⁸⁷ “Policy Bulletin Regarding Laser Hair Removal,” *Massachusetts Office of Consumer Affairs & Business Regulation (OCABR) (website)*. <http://www.mass.gov/ocabr/licensee/dpl-boards/et/regulations/et-board-policies/policy-06-01.html>

⁸⁸ Per Rebecca Rodman, Esq., Staff Counsel to the Board of Registration of Medicine.

⁸⁹ See the Texas Department of State Health Services website for full particulars and links to the applicable statutes and regulations: <http://www.dshs.state.tx.us/radiation/laserhair.shtm>

⁹⁰ See 215 ILCS 412/223-4 reproduced as Appendix D:
<http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1352&ChapterID=24>

⁹¹ Tennessee (see “General Rules Governing Electrology, Electrologists, and Electrology Instructors,” <http://www.tn.gov/sos/rules/0540/0540-01.20100523.pdf>) and Vermont (see Appendix B) absolutely permit electrologists to engage in the practice of laser hair removal without any supervision. Both Illinois and Florida permit electrologists to engage in laser hair removal under medical supervision (see Appendices A & D). Texas does not license electrology as a profession but recently enacted legislation that would appear to permit electrologists upon certification to be licensed as a “Laser Hair Removal Professional” and thereafter to engage in laser hair removal under off-premises medical supervision.
<http://www.dshs.state.tx.us/radiation/laserhair.shtm>

HEALTH CARE PROFESSIONS THAT CAN REASONABLY BE ANTICIPATED TO BE DIRECTLY AFFECTED BY THE REQUEST, THE NATURE OF THE IMPACT, AND EFFORTS MADE BY THE REQUESTOR TO DISCUSS IT WITH SUCH HEALTH CARE PROFESSIONS

All licensed Connecticut physicians and their extenders (RNs and PAs) who currently deliver laser cosmetic hair removal or reduction services will be impacted by this scope of practice request. To date, it is the perceived position of all physician groups who have intervened that electrologists only be permitted to operate laser hair removal devices under their direct supervision, presumably as their employees.

ECONOMIC IMPACT OF THE REQUEST ON THE HEALTH CARE DELIVERY SYSTEM

IMPACT OF THE REQUEST ON PUBLIC ACCESS TO HEALTH CARE

Laser hair removal procedures are virtually always cosmetic and elective. Electrologists are only trained and licensed to remove unwanted body and facial hair. They have no other services to render without re-training. In contradistinction, all of the physicians, APRN's, RN's and PA's currently engaged laser hair removal/reduction services are able to render other health care delivery services. As the demand for hair removal services through electrolysis declines, the use of electrologists to meet some of the increasing demand for laser hair removal services will, all things being equal, relieve pressure on the rise of health care delivery costs in Connecticut and improve public access to health care by lessening the load on other health care personnel.

PUBLIC HEALTH AND OTHER BENEFITS THAT MAY BE REALIZED BY PERMITTING ELECTROLOGISTS TO USE LASER HAIR REMOVAL DEVICES

The CSEA believes that there are two public health benefits that will be conferred on the residents of Connecticut by approval of this request.

First, advanced medical practitioners such as surgeons, physicians, PA's, and RN's, currently obliged to meet the public demand for removal or reduction of unwanted hair, will be freed up to treat more patients more quickly for their medical problems when relieved of cosmetic duties.

Second, considering there are currently no formal training requirements for the PA's and RN's who typically operate laser devices in Connecticut, if supplementally-trained electrologists are permitted to operate laser hair removal devices in Connecticut, the quality of the operators will improve. It follows that some of the many people from our state who travel to New York to obtain lower-cost hair removal services from unlicensed personnel who frequently are used to staff clinics there will procure these services here. These Connecticut residents thus should experience fewer bad outcomes from treatment. Furthermore, the State of Connecticut will benefit by realizing revenue from the imposition of sales tax on these procedures (which are now being performed in

adjoining states) when they are performed in Connecticut as laser hair removal services are now taxable.⁹² Given the state's budget crisis, this additional revenue is badly needed. Furthermore, the purchase by electrologists in Connecticut of equipment, supplies and business services will inject into the Connecticut economy all the money currently being spent on laser hair removal services by Connecticut residents that are actually delivered in New York and Massachusetts.⁹³

CLAIMS MADE BY PHYSICIANS

Notwithstanding, and as physicians have done elsewhere in the United States where non-physicians have sought to use laser hair removal devices,⁹⁴ several physicians' professional organizations have previously opposed the use of laser medical devices by electrologists, including the Connecticut Society of Eye Physicians, the American Academy of Ophthalmology, the Connecticut Dermatology and Dermatologic Society, the American Academy of Dermatology Association, the American Academy for Dermatologic Surgery Association, the Connecticut Dermatology & Dermatologic Surgery Society, the Connecticut Medical Society, and the Connecticut Society of Plastic and Reconstructive Surgeons. Their professed reason for opposing the request is the belief that the public health will be jeopardized and that additional demands will be placed on the health care delivery system in Connecticut if electrologists are permitted to use hair removal or reduction lasers. In reviewing the submissions of the various medical organizations and their representatives, the primary specifications can be reduced to the following.

- 1) Electrologists lack the ability to identify pre-existing or underlying medical conditions that may cause unwanted hair growth, and to diagnose and treat them.
- 2) Electrologists lack the ability to identify contraindications to laser hair removal treatment.
- 3) Laser hair removal performed by untrained personnel may cause burns and scarring.
- 4) Laser hair removal requires topical anesthetics which have significant risks associated with their use.
- 5) Electrologists lack the ability to immediately treat any complications from laser hair removal.

⁹² Connecticut is now levying a sales tax on cosmetic laser services which include laser hair removal. See the State of Connecticut Department of Revenue Services website, <http://www.ct.gov/drs/cwp/view.asp?a=1514&q=482490>

⁹³ New York allows cosmetologists (among others) to perform laser hair removal services. See "Consumer Guide to Beauty Salons & Spas," New York Department of State. http://www.dos.ny.gov/licensing/pdfs/beauty_salon_guide.pdf. In Massachusetts, some electrologists continue to operate laser hair removal devices.

⁹⁴ For a treatment of this topic see Laura J. Sanger, "Laser Hair Removal," *Health Law Perspectives* (Web Publication), 8 April, 2008. [http://www.law.uh.edu/healthlaw/perspectives/2008/\(LSK\)%20laser.pdf](http://www.law.uh.edu/healthlaw/perspectives/2008/(LSK)%20laser.pdf)

- 6) Treatment of complications caused by undertrained and/or unsupervised electrologists will place additional demands on the health care delivery which outweigh the benefits of permitting electrologists to provide laser hair removal services.

Regarding specification 1, that electrologists lack the ability to identify pre-existing or underlying medical conditions that may cause unwanted hair growth and to diagnose and treat them, CSEA agrees that electrologists lack the ability to treat medical or hormonal problems that may be the underlying cause of hirsutism⁹⁵ or hypertrichosis. As practicing electrologists, they bump up against these conditions daily and receive formal training in the science of trichology as part of their electrology instruction and are trained to advise patients to consult physicians when these conditions are recognized. Pre-treatment clearance by a physician will reduce the possibility of contraindicated treatment.

Regarding specification 2, that electrologists lack the ability to identify contraindications to laser hair removal treatment, the CSEA view is that with supplemental training, use of checklists,⁹⁶ The Fitzpatrick Skin typing test,⁹⁷ pre-treatment patch-testing during patient intake, and mandatory pre-treatment clearance of patients by physicians, these concerns will be addressed. According to the American Academy of Dermatology, the purpose of a pre-treatment consultation is “to ascertain skin type (i.e. the ability to tan or burn), hair color, thickness and location of hair, presence of tan, previous hair removal methods, medical history (including ovarian or thyroid disease, medications, history of cold sores (herpes simplex), outbreaks in the treatment area, or past isotretinoin use) and the presence of tattoos or moles in the treatment area.”⁹⁸ Although electrologists are already trained to screen patients prior to performing electrolysis for these conditions, mandatory physician clearance for treatment should assuage these concerns.⁹⁹

Regarding specification 3, that laser hair removal performed by untrained personnel may cause burns and scarring, the CSEA agrees this is a possibility which can be controlled as a risk by supplemental training in the use of the devices and selection of patients including use of the Fitzpatrick Skin typing test and pre-treatment patch testing,¹⁰⁰ and the employment of newer equipment with cooling capabilities. Superficial burns are a routine side effect of both laser hair removal and electrolysis, as thermolysis is the method both employ for tissue destruction. The 1997

⁹⁵ According to Christine Dierickx, a leading laser hair removal researcher, female patients with hirsutism, regardless of cause, may receive laser hair removal treatment. See Dierickx, op. cit., 6.

⁹⁶ It has been recommended that patients with a history of keloid scar formation or who have been treated with isotretinoin within the previous year not undergo laser hair removal. See L. Hobbs, "Synopsis of Laser Assisted Hair Removal Systems," *Skin Therapy Letter* 5 (2000). <http://www.skintherapyletter.com/2000/5.3/1.html>

⁹⁷ The Fitzpatrick Scale (aka Fitzpatrick skin typing test or Fitzpatrick photo-typing scale) is a numerical classification schema for the color of skin. It was developed in 1975 by Thomas B. Fitzpatrick, a Harvard dermatologist, as a way to classify the response of different types of skin to ultraviolet light. It remains a recognized tool for dermatologic research into the color of skin.

⁹⁸ "Laser Hair Removal," *American Academy of Dermatology (website)*.

<http://www.aad.org/media-resources/stats-and-facts/cosmetic-treatments/laser-hair-removal>

⁹⁹ A comprehensive History Health Assessment form developed with physician assistance is available to electrologists from the American Electrology Association: <http://www.electrology.com/electrologist/store.html?cat=1>

¹⁰⁰ A small patch of the patient's skin is treated and observed a week later to determine patient reaction and assist the operator in selecting proper fluence and other settings during actual treatment.

Connecticut Board of Medical Examiners decision indicates delegation by physicians of actual device operation is appropriate.

Regarding specification 4, that laser hair removal requires topical anesthetics which have significant risks associated with their use, the web is replete with physician advertisements touting laser hair removal as virtually painless.¹⁰¹ The American Academy of Dermatology web pamphlet entitled "Laser Hair Removal" states, "The laser pulses feel like the snapping of rubber bands or warm pinpricks against the skin."¹⁰² Newer laser hair removal devices incorporate cooling technology which permits skin to be cooled when the laser is fired. This results in a significant reduction in non-targeted skin heating and resulting pain. Electrolysis, which is described in the medical literature as more painful than laser hair removal, has traditionally been performed without prescription topical anesthetics. **One must also remember that hair removal is virtually always an elective and cosmetic procedure.** Persons who are more sensitive to pain may always choose to engage a physician-operated or supervised clinic in which to have the procedure performed, where a topical anesthetic may be applied. (But one must be wary of those. Several of the physicians' associations have cited the FDA Public Health Advisory of February 6, 2007 on Topical Anesthetics¹⁰³ as grounds to deny this request citing potential misuse by patients or electrologists of topical anesthetics. That Public Health Advisory cautioned on the misuse of topical anesthetics when in two separate incidents in 2004 and 2005 young women died after applying excessive amounts of specially compounded topical anesthetic gels¹⁰⁴ to their bodies prior to undergoing laser hair removal procedures.¹⁰⁵ In both cases, physicians (one was a plastic surgeon¹⁰⁶) operated the involved med-spas. The gels were improperly prescribed and dispensed by these physicians, and they were neither FDA-approved or accompanied by warnings or use directions, and the pharmacies compounding them were violating federal laws in so doing.¹⁰⁷ There is no evidence that

¹⁰¹ Patrick R. Felice's website states that "Anesthesia is not required and most individuals experience no more than a slight stinging sensation..."

<http://youthfulimages.com/services/non-surgical-services/laser-hair-removal>

¹⁰² "Laser Hair Removal," *American Academy of Dermatology (website)*.

<http://www.aad.org/media-resources/stats-and-facts/cosmetic-treatments/laser-hair-removal>

¹⁰³ Available at

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/PublicHealthAdvisories/ucm054718.htm>, or view the podcast at

<http://www.fda.gov/Drugs/DrugSafety/DrugSafetyPodcasts/ucm079047.htm>

¹⁰⁴ One was called "Lasergel Plus 10/10," a 10% lidocaine and 10% tetracaine preparation. The other was called "Photocaine," a 6% lidocaine and 6% tetracaine preparation.

See "Laser Client Died of Lidocaine Overdose," *Electrolysis News* (Spring 2005):16-17.

<http://www.hairroute.com/subscriber/news/electrolysisnews0305.pdf>

Also see Leslie Goldman, "Go Easy on Medicated Lotions, Creams, Gels," *CNN.com* (5 February 2008).

http://articles.cnn.com/2008-02-05/health/healthmag.creams_1_creams-methyl-salicylate-hair-removal/3?s=PM:HEALTH

¹⁰⁵ "University Pharmacy on Notice," *PCO University (website)*.

<http://pcouniversity.com/University-Pharmacy-on-notice.html>

¹⁰⁶ "Medical Board Recommends Spa Doctor Lose License for Six Months," *WRAL (website)*.

<http://www.wral.com/news/local/story/1091035/>

¹⁰⁷ "Tragic Deaths Related to Pharmacy Compounded High-Strength Lidocaine/Tetracaine Creams," *Institute for Safe Medication Practices (website)*. <http://www.ismp.org/newsletters/acutecare/articles/20050210-1.asp>

Also see "Warnings for Makers of Compounded Pain Products," *Highbeam Business (website)*.

http://goliath.ecnext.com/coms2/gi_0199-6396334/Warnings-for-makers-of-compounded.html

electrologists or persons trained as electrologists were involved in either incident.) Electrologists are not seeking any prescribing authority with this request.

Specification 5 is that electrologists lack the ability to immediately treat any complications from laser hair removal. Complications from laser hair removal have been listed as burning, scarring, pigmentary changes, post treatment erythema and edema, reticulate erythema or ocular complications, pain, and purpura.¹⁰⁸ None of these complications are life-threatening.¹⁰⁹ For redness and swelling in the aftermath of laser hair removal, the American Academy of Dermatology recommends application of over-the-counter topical steroids.¹¹⁰ According to the Mayo Clinic, the treatment protocol for first and second degree burns no larger than 3 inches in diameter: cool the burn with running water or cold compresses, then cover it with sterile gauze bandage; take an over-the-counter pain reliever and to talk to your doctor if you have concerns.¹¹¹ The American Academy of Dermatology in its patient handout pamphlet entitled "Laser Hair Removal"¹¹² further recommends treatment of blisters with topical antibiotics as does Web MD, specifically mentioning Bacitracin or Polysporin, both available over the counter.¹¹³ Third degree burns do require medical attention (but should never occur if the devices are being operated according to specifications and are properly maintained, patch tests have been performed in advance of treatment, and the operators have been trained on the use of the device). Infrequent ocular complications, such as uveitis, will in any event need to be treated by an eye specialist (typically not present in physician operated medi-spas, dermatologists' or plastic surgeons' offices). Pigmentary changes (hypopigmentation or hyperpigmentation) and purpura are not medical problems but rather terms of description. Like post-treatment erythema and edema, they are predictable and usually transient consequences of destruction of hair follicles according to the American Academy of Dermatology.¹¹⁴

Specification 6 is that treatment of complications caused by undertrained and/or unsupervised electrologists will place additional demands on the health care delivery system which outweigh the benefits of permitting electrologists to provide cosmetic laser hair removal services. For this to be true, the dollar costs of treating injuries for side-effects (they are described in specification 5, above) to patients as a result of poor judgment or improper operation by

"FDA Warns Five Firms to Stop Compounding Topical Anesthetic Creams." *U.S. Food and Drug Administration (website)*. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108793.htm>

¹⁰⁸ Vano-Galvan, S. and Jaen, P., "Complications of Non-Physician Supervised Laser Hair Removal." *Canadian Family Physician* 55 (2009): 50-52. <http://www.cfp.ca/content/55/1/50.full.pdf+html>

¹⁰⁹ The website of Alicia Zalka, M.D., a Connecticut dermatologist, regarding possible adverse effects states: "The following temporary side effects have been noted in a small percentage of patients treated: slight redness (usually resolves within a few days), lightening or darkening of the skin (usually resolves within weeks to months), superficial burns (usually resolve within a week) and blisters (usually resolve within a few weeks)." http://www.dermwestconn.com/descriptions/laser_hair_desc.html

¹¹⁰ "Laser Hair Removal," *American Academy of Dermatology (website)*. <http://www.aad.org/media-resources/stats-and-facts/cosmetic-treatments/laser-hair-removal>

¹¹¹ "Burns: First Aid," *Mayo Clinic (website)*. <http://www.mayoclinic.com/health/first-aid-burns/FA00022>

¹¹² <http://www.aad.org/store/patient-education/pamphlets/pamphlets?sku=/store/product?id=100>

¹¹³ "Home Treatment for Second-Degree Burns: Topic Overview," *Mayo Clinic (website)*. <http://www.webmd.com/skin-problems-and-treatments/tc/home-treatment-for-second-degree-burns-topic-overview>

¹¹⁴ See "Laser Hair Removal," *American Academy of Dermatology (website)*. <http://www.aad.org/media-resources/stats-and-facts/cosmetic-treatments/laser-hair-removal> Dr. Sergio Vano-Galvan concurs and further suggests a low strength topical steroids (e.g. Cortisol, available over the counter in any drug store or supermarket) for inflammation.

electrologists would have to exceed the dollar value of the practice time of MDs, RNs, and PAs that would have been devoted to those laser cosmetic hair removal services now performed by electrologists. This is very improbable. One way of evaluating this assertion is to examine the type and nature of serious injuries that have occurred in connection with operation of cosmetic lasers while engaged in hair removal. One available source of information is the MAUDE¹¹⁵ “adverse events” reports from the manufacturers and operators of devices which might have been involved in causing injuries. These are mandatory and they are available at the FDA’s website.¹¹⁶

A total of 61 adverse incident reports involving laser hair removal in which 88 persons were reported injured were filed during the period 1/1/2009 through 12/31/2011 with respect to laser hair removal devices used in the United States. A total of 14 reports were filed in which 20 persons were reported as injured in 2011. A total of 25 reports were filed in which 31 persons were reported as injured in 2010. A total of 22 reports were filed in which 37 persons were reported as injured in 2009. Thus, there were reports of 85 injuries during the period 2009-2011. After a close review of each of the reports filed during that period, it appears that 3 of the reported injuries should be removed from the stats (1 involved a laser purchased for home use, 1 was determined to have a psychiatric origin with no actual injury, and in 1 the patient was reported injured in a non hair removal procedure which was reported along with a hair removal incident involving the same machine) reducing the total injured patients to 85. Of the 85 injuries, eight were determined to result from the failure conduct a patch test on the patient, seven were determined to be the result of over-treatment, eight were determined to be the result of operator error in selecting settings or exercising poor technique with the hand device, 26 were determined to be the result of poor equipment maintenance (of which the vast majority were the failure to keep the treatment tip on the hand tool clean), two were due to treating patients who had recently achieved tans, one was due to failure to calibrate the device correctly, one was due to failure to shave the area being treated prior to treatment, one was due to the treatment of a sex organ and may also have a psychiatric origin as it was patient-reported, one was due to treatment of a patient who by virtue of having taken a medication a year previously was determined to be hyper-photosensitive, and in 30 of the cases, the cause of the injuries could not be determined.

Of the 85 persons sustaining injuries during the period, twelve were injured while the devices were being operated by MDs, four when by RNs, 64 when by “health professionals,” which could include physicians, nurses, physicians’ assistants, laser technicians, and electrologists if licensed by a health authority. Four were reported to have occurred while the devices were operated by others and one states “unknown operator.”

Of the 85 affected, 58 were reported as having burns (four third-degree burns, 54 first- or second-degree burns), nine reported scarring, seven reported blisters, two reported redness or inflammation, six reported hypo-pigmentation, two reported swelling, and one reported an “adverse reaction.” Not a single case of eye injury was reported during the period.

¹¹⁵ See 21CFR 803. MAUDE is an acronym for “Manufacturer and User Facility Device Experience.” The FDA’s website provides details regarding the method of reporting. See “Reporting Adverse Events (Medical Devices),” *U.S. Food and Drug Administration (website)*.

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>

¹¹⁶ “MAUDE- Manufacturer and User Facility Device Experience.” *U.S. Food and Drug Administration (website)*.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/textsearch.cfm>

A significant percentage of the injuries reported sustained (30.5%) were the result of failure to maintain the devices, almost always from failure to clean the treatment tip. Only one case was reported where a pre-existing condition or contraindication of a medical nature (hyper-photosensitivity due to the patient having been on a medication a year prior to treatment) might have been avoided by screening. One must remember that in a significant percentage of the reported injuries (35%) a cause was not susceptible of determination by the information available. One must also consider the likelihood that, although the reporting is mandatory, many minor injuries likely went unreported.

When one considers the number of laser hair removal procedures that are likely to have been performed during the same period, which by extrapolation from the marketing research statistic cited previously must have been at least 9 million, the rate of poor outcomes is quite small.

According to Sergio Vano-Galvan, M.D., "overall incidence of adverse effects after laser hair removal appears to be low and transient."¹¹⁷

A review of the effects of laser hair removal done in 2006 concludes that laser hair removal is a safe procedure and that the majority of adverse effects are transient and minor, with a very low incidence of permanent adverse outcomes.¹¹⁸

Laser technology is now so safe that in 2008, TRIA Beauty received FDA clearance for its TRIA Laser Hair Removal System, and began marketing the device to consumers for use at home. Its highest output setting, 22 Joules/cm², is equivalent to devices used professionally, although at 10 mm diameter its spot size is somewhat smaller.¹¹⁹

EXAMPLES OF SUPPLEMENTAL TRAINING INDICATED FOR USE OF LASER AND IPL HAIR REMOVAL/REDUCTION DEVICES

As previously mentioned, several states have recently legislated in the field of laser hair removal. The rules concerning the type and nature of training required for electrologists to operate

¹¹⁷ Vano-Galvan, S. and Jaen, P., "Complications of Non-Physician Supervised Laser Hair Removal." *Canadian Family Physician* 55 (2009): 50-52. <http://www.cfp.ca/content/55/1/50.full.pdf+html>

¹¹⁸ Lanigan et al, "A Review of the Adverse Effects of Laser Hair Removal." *Lasers in Medical Science* 21 no. 3 (2009):121-125.
<http://www.ncbi.nlm.nih.gov/pubmed?term=Lanigan%20A%20review%20of%20the%20adverse%20effects%20of%20laser%20hair%20removal>.

¹¹⁹ The TRIA Laser Hair Removal System (LHRS) is priced at \$395. The device is a little smaller than a typical hair dryer, weighing 1.36 lbs, and measuring 8 x 4.5 x 3 inches. It contains an AlGaAs (aluminum gallium arsenide) laser diode array at 810 nm and produces about 40 W with five output levels of 6, 8, 12, 16, and 22 J/cm² with a 10 mm spot size. The class I laser reportedly will not cause retinal damage at any viewing distance. See <http://www.bioopticsworld.com/articles/print/volume-3/issue-1/departments/news-views/optical-as-accurate.html>

light-based hair removal devices of several of these (Texas, Florida, North Carolina and Vermont) will be reviewed below, illustratively, as each has taken a somewhat different approach.

TEXAS

The “Texas Registration and Radiation Safety Requirements for Use of Laser Hair Removal Devices”, 25 Texas Administrative Code 289.302 were adopted in 2010 and are available at the Texas State Department of Health website.¹²⁰ Non-medical professionals (including electrologists, since Texas does not recognize electrology as a profession), before operating laser hair removal equipment without supervision, must have (1) at least 24 hours of training in laser hair removal device safety, laser physics, skin typing, skin reactions, treatment protocols, burns, eye protection, emergencies, and post-treatment protocols; and (2) an additional 16 hours of training in cardio-pulmonary resuscitation (a valid cardio-pulmonary resuscitation certificate may be used to satisfy up to 8 hours of the that training), a review of client's pre-existing conditions to determine if consultation with a consulting physician is needed for possible diagnosis or treatment, a review of client's previous hair removal procedures by another modality, a review of client's current medications to determine if any medications need to be brought to the attention of the consulting physician based on established protocols, proper signage and posting, use of a laser hair removal device and anesthesia used in conjunction with laser hair removal procedures provided by a training program and provider approved by the Texas State Dept. of Health; and (3) documented at least 100 supervised laser hair removal procedures within the prior year.¹²¹ Additionally, each laser hair removal facility must have a “laser safety officer” whose qualifications shall include at least the following: educational courses related to laser radiation safety, a Laser Safety Officer course, or familiarity with and experience in the use of laser hair removal devices; and knowledge of potential laser radiation hazards and laser emergency situations. His responsibilities and duties include, but are not limited to, (1) ensuring that users of LHR devices are trained in laser safety; (2) assuming control and having the authority to institute corrective actions, including shutdown of operations when necessary, in emergency situations or if unsafe conditions exist;(3) ensuring that maintenance and other practices required for safe operation of the LHR devices are performed; (4) ensuring the proper use of protective eyewear and other safety measures; (5) ensuring compliance with the requirements in this section and with protocols specified by the registrant; (6) ensuring audits required (to verify operator training requirements have been met and the “consulting physician” is performing his or her duties); (7) maintaining required records; and (8) ensuring that personnel are adequately trained, certified, and in compliance with the regulations.

Were electrology recognized as a profession in Texas, it is unclear what supplemental requirements, if any, a practicing electrologist would need to operate laser hair removal devices.¹²²

¹²⁰ “Laser Hair Removal- Radiation Control Program,” *Texas Department of State Health Services (website)*. <http://www.dshs.state.tx.us/radiation/laserhair.shtm>

¹²¹ See “25 Texas Administrative Regulations 289.302(r)” at “Laser Hair Removal- Radiation Control Program,” *Texas Department of State Health Services (website)*. <http://www.dshs.state.tx.us/radiation/laserhair.shtm>

¹²² In addition to “grandfathering” provisions that limit the applicability of the clinical training requirements to existing providers, the Texas regulations include the following provisions: “(7) A health professional licensed under another law is not required to hold a certificate to perform laser hair removal procedures issued in accordance with this section if the performance of laser hair removal is within the scope of that professional's practice as determined by the professional's

A senior laser hair removal technician may obtain certification as a Certified Laser Hair Removal Professional (CLHRP) by the International Commission for Hair Removal Certification (ICHRC), the accrediting body of The Society for Clinical and Medical Hair Removal, Inc. (SCMHR), by passing a multiple-choice question examination before engaging in independent laser hair removal device operation. (This, together with a contract with a consulting physician and the engagement of a LSO, would permit independent practice.)¹²³

NORTH CAROLINA

In 2010 North Carolina extended to licensed electrologists the authority to operate laser hair removal devices as “laser hair practitioners” by completion of a 30 hour supplemental education program provided their practice was under the off-site supervision of a physician in accordance with a “Supervisory Agreement” between the physician and electrologist which must be filed with the Board of Examiners in Electrology.¹²⁴ The contents of the supervisory agreement are not further articulated. The course of study for laser hair removal consists of at least 30 hours of instruction in theory and clinical practice, with a minimum of 20 hours in practical hands-on instruction and at least 10 hours of basic science (didactic) instruction in the use of laser and light-based hair removal or reduction devices in the following topics: (1) biology of hair; (2) laser and light-based terminology; (3) laser physics; (4) types of laser and light-based hair removal devices; (5) safety and precautions; (6) tissue interaction; (7) Fitzpatrick skin typing; (8) patient history form and consultation; (9) treatment contraindications; (10) sterilization procedures; (11) draping of patient; (12) pre-treatment and post-treatment care; (13) photo documentation; and (14) photosensitive drugs and disorders.¹²⁵

FLORIDA

In Florida, electrologists are regulated by the Board of Medicine, which adopted regulations in 2008 allowing licensed electrologists who complete a 30 hour curriculum and receive certification as a Certified Medical Electrologist (CME) by the International Commission for Hair Removal Certification (ICHRC) to operate laser hair removal/reduction devices under the off-site supervision

licensing board, and (8) The qualifications for eligibility for an applicant for a senior LHR technician certificate who is a licensed health professional shall be established by the entity that issues licenses for that health profession.”

¹²³ See “Certification,” *The Society for Clinical & Medical Hair Removal, Inc. (website)*.

<http://www.scmhr.org/clinicians/testing.php>

Also see “Laser Hair Removal- Radiation Control Program,” *Texas Department of State Health Services (website)*.

<http://www.dshs.state.tx.us/radiation/laserhair.shtm#Reg>

¹²⁴ The salient portions of the authorizing statute are reproduced in Appendix E.

The laser hair removal technician required curriculum is available at <http://ncrules.state.nc.us/ncac/title%2021%20-%20occupational%20licensing%20boards%20and%20commissions/chapter%2019%20-%20electrolysis%20examiners/21%20ncac%2019%20.0601.pdf>

¹²⁵ The curriculum is available at the website of the North Carolina Board of Examiners in Electrolysis at <http://ncrules.state.nc.us/ncac.asp?folderName=/Title 21 - Occupational Licensing Boards and Commissions/Chapter 19 - Electrolysis Examiners>.

of a physician.¹²⁶ The curriculum consists of 30 hours of instruction, which may include 15 hours of home-study didactic training, in the use of laser and light-based hair removal or reduction devices, including the following: (1) biology of hair; (2) laser and light-based device terminology; (3) basic electricity; (4) laser and light-based hair removal physics, including the theory of traditional light, the theory of coherent light, the electromagnetic spectrum, the different types of laser and light-based hair removal devices, the history of laser and light-based device development, the history of medical laser and light-based device development, understanding photonic principles and how a laser and light-based device works, and hair removal laser and light-based device delivery systems; (5) safety and precautions, including federal and quasi-federal regulatory agencies and their roles in safety, treatment room considerations, eye safety for the operator and the patient, and fire safety; (6) laser and light-based tissue interaction, including Grotthuss-Draper¹²⁷ law, reflection, transmission, scatter and absorption, the melanin and hemoglobin absorption curve at various hair removal device wavelengths, depth of penetration and wavelength, possible effects of absorption of light energy; selective photothermolysis, including wavelength, pulse duration, energy fluence, and spot size; sanitation, Fitzpatrick skin typing, patient intake form, the consultation, proper documentation of patient case history and consent forms, pre-treatment patient preparation including test spot considerations and Nikolsky's sign;¹²⁸ treatment contra-indications including the recognition of disease conditions of the skin; handpiece and spot size considerations, fluence setting, stretch technique, use of grid stamp; post-treatment procedures, including: application of ice and medication, instructions to patients, expected outcomes including erythema and edema; possible adverse outcomes, follow-up care, the concept of using needle-type epilators to complement laser and light-based hair removal or reduction devices; and at least 5 hours of hands-on experience with laser and light-based devices to include hair removal or reduction from all areas of the body.¹²⁹

VERMONT

¹²⁶ See Appendix A

¹²⁷ The Grotthuss–Draper law (also called the Principle of Photochemical Activation) states that only that light which is absorbed by a system can bring about a photochemical change. Materials such as dyes and phosphors must be able to absorb light at optical frequencies. This law provides a basis for fluorescence and phosphorescence. The law was first proposed in 1817 by Theodor Grotthuss and in 1842, independently, by John William Draper. "Photoelectrochemical Processes," *Wikipedia, the Free Encyclopedia*. http://en.wikipedia.org/wiki/Grotthuss%E2%80%93Draper_law (Accessed 13 August 2012).

¹²⁸ Nikolsky's sign is a clinical dermatological sign named after the Russian physician Pyotr Nikolsky (1858–1940). The sign is positive when slight rubbing of the skin results in exfoliation of the outermost layer. Nikolsky's sign is almost always present in toxic epidermal necrolysis and is associated with pemphigus vulgaris. It is useful in differentiating between pemphigus vulgaris (where it is present or positive) and bullous pemphigoid (where it is absent). "Nikolsky's Sign," *Wikipedia, the Free Encyclopedia*. http://en.wikipedia.org/wiki/Nikolsky%27s_sign (Accessed 13 August 2012).

¹²⁹ See Florida Administrative Code explanation:
"Rule: 64B8-52.004," *Florida Department of State, Division of Library and Information Services*.
<https://www.flrules.org/gateway/ruleno.asp?id=64B8-52.004>

Vermont simply enacted a statute that expanded the definition of “electrology” to include the use by “properly trained” licensed electrologists of lasers approved by the United States Food and Drug Administration...as otherwise permitted by Vermont law.¹³⁰ There are not available any published regulations by the Department of the Vermont Office of Professional Regulation explicating the meaning of “properly trained’ as yet.

PROPOSED SUPPLEMENTAL CURRICULUM FOR ELECTROLOGISTS DESIRING TO OPERATE LASER AND IPL HAIR REMOVAL DEVICES IN CONNECTICUT

The CSEA is suggesting a 40 hour curriculum as set forth in Appendix G, which would include up to 15 hours in home study didactic education. There are two schools, each currently approved by the Department of Health and the Connecticut Board of Electrology Examiners for their programs in electrolysis instruction, who offer equivalent programs of educational instruction in light based hair removal.¹³¹ The electrologist shall further undergo examination and receive certification as a Certified Medical Electrologist (CME) by the International Commission for Hair Removal Certification (ICHRC) the accrediting body of The Society for Clinical and Medical Hair Removal, Inc. (SCMHR).

AREAS FOR REGULATORY ACTION BY THE DEPARTMENT OF PUBLIC HEALTH

CSEA believes that it may be appropriate for the Department of Public Health in its discretion to adopt safety guidelines for operation of laser hair removal devices by electrologists, examples of which are available from Rockwell Laser Industries at <http://www.rli.com/> which provides industry-wide laser safety solutions, consulting and training and to the British Columbia Centre for Disease Control which has promulgated safety guidelines for owners and operators of laser hair removal establishments and which are available at: <http://www.health.gov.bc.ca/library/publications/year/2011/Laser-hair-removal-guidelines.pdf>

¹³⁰ See Appendix B.

¹³¹ *The Berkowits School of Electrolysis, Inc. (website)*. <http://www.berkowitzschool.com/>
Laser Hair Institute (website). <http://laserhairinstitute.com/>
"Curriculum," *Laser Hair Institute (website)*. <http://laserhairinstitute.com/id2.html>
"More information," *Laser Hair Institute (website)*. <http://laserhairinstitute.com/id3.html>
Hollywood Institute of Beauty Careers (website). http://hi.edu/beauty_school/laser_hair.html

WHY PUBLIC HEALTH IS BETTER SERVED IF ELECTROLOGISTS ARE PERMITTED TO OPERATE WITHOUT DIRECT PHYSICIAN SUPERVISION

There have been very few valid complaints against electrologists lodged with the Department of Health or the Board of Examiners of Electrology over the past several decades. Members of the profession have comported themselves appropriately and have rendered considerable benefits to the residents of Connecticut by providing competent and reliable permanent hair removal services without physician supervision, direct or indirect. Historically, electrologists in Connecticut have been sole proprietors or partnerships with very few partners. It will be very expensive for each such economic unit of practicing electrologists to contract with a physician to provide off-premises oversight and auditing services. These costs will have to be recouped somehow, and that typically means higher procedure costs for patients than they would otherwise incur. The time that physicians must expend on this oversight and auditing role for elective cosmetic procedures will be subtracted from the time they have to spend on medical care. The pre-treatment screening that opponents of this scope of practice request have demanded for elective cosmetic laser and IPL hair removal procedures will also further reduce the time they and their staff have for providing care and treatment to residents with medical problems. Their fees will, again, wind up being paid by the patient. In all likelihood, these types of exams or consultations will be assigned to junior staff in their offices, and it really becomes a question of whether a PA or RN in a general practitioner's or internist's office is going to provide any significant improvement in risk reduction to the patient. In the opinion of CSEA, mandatory physician off-premises supervision or pre-treatment screening is not at all justified by risk reduction in adverse outcomes, it and amounts to a barrier to entry of electrologists into the laser and IPL hair removal market in Connecticut.

A DESCRIPTION OF HOW THE REQUEST RELATES TO THE HEALTH CARE PROFESSION'S ABILITY TO PRACTICE TO THE FULL EXTENT OF THE PROFESSION'S EDUCATION AND TRAINING

Connecticut currently has 164 licensed electrologists, many of whom are eager and willing to obtain supplemental training to permit them to safely and responsibly use 21st-century solutions to the science of cosmetic hair removal. Failure to extend this opportunity to those who desire to do so will result in the likely exodus of many more trained and very experienced professionals from this field of cosmetic hair removal over the next decade which will be a great loss to the thousands of Connecticut residents who desire safe and effective removal of unwanted body and facial hair.

APPENDIX A

(Florida)

Florida Administrative Code, Department 64, Department of Health, Division 64B8. Board of Medicine, Chapter 64B8-56.

Standards

§ 64B8-56.002. Equipment and Devices; Protocols for Laser and Light-Based Devices

(1) The Board of Medicine approves the following equipment and devices for the permanent removal of hair by licensed electrologists if they are used pursuant to requirements established by the Board.

(a) Needle type epilators.

(b) Laser and light-based hair removal or reduction devices cleared by the United States Food and Drug Administration (FDA) for hair removal or reduction.

(2) An electrologist may not use laser or light-based devices for hair removal or reduction unless they:

(a) Have completed training in laser and light-based hair removal and reduction that meets the requirements set forth in Rule 64B8-52.004(2) and (3), F.A.C.;

(b) Have been certified in the use of laser and light-based devices for the removal or reduction of hair by a national certification organization approved by the Council and the Board;

(c) Are using only the laser and light-based hair removal or reduction devices upon which they have been trained; and

(d) Are operating under the direct supervision and responsibility of a physician properly trained in hair removal and licensed pursuant to the provisions of Chapter 458 or 459, F.S.

(3)(a) The supervising physician, initially upon assuming duties as the supervisor and semiannually thereafter, shall review and inspect the techniques, procedures, and equipment utilized by the electrologist in the performance of laser and light-based hair removal or reduction.

(b) The supervising physician shall ensure that the electrologist has received semi-annual training in the areas of infection control, sterilization, and emergency procedures.

(4)(a) The supervising physician and the electrologist shall develop jointly written protocols regarding the medical condition for individuals to receive laser and light-based hair removal or reduction treatment; specific conditions and the procedure for identifying conditions that require direct evaluation or specific consultation by the physician; treatment of routine minor problems resulting during or from laser and light-based hair removal or reduction; and detailed procedures to be followed in the event of emergency situations developing during the performance of or as a result of laser and light-based hair removal or reduction. These written protocols must be signed, dated, and maintained in a readily available location on the premises where the electrologist practices. One copy shall be maintained by the supervising physician and one copy must be filed with the Department of Health. The written protocols which are kept on the premises of the electrologist will be readily available for inspection and review by agents of the Department of Health or the Board of Medicine. The parties to a protocol must notify the Department within 30 days of the termination of their professional relationship.

(b) The written protocol shall include and require that the initial consultation with each patient must include an examination and assessment by a physician licensed pursuant to Chapter 458 or 459, F.S.

(c) The written protocol shall include a statement that the electrologist does and will maintain professional liability coverage that includes coverage for incidents arising from laser usage in an amount not less than \$100,000.

(5) Pursuant to Section 456.072(1)(i), F.S., any physician who knows that any electrologist is engaged in unsafe practice must report that electrologist to the Department of Health immediately.

(6) Any physician who provides supervision to an electrologist must keep the Board informed of the number of electrologists the physician is supervising. No physician is authorized to supervise more than four (4) electrologists at any one time.

History. Specific Authority 478.43 FS. Law Implemented 458.331(1)(v), 458.348(3), 478.42(5), 478.43(4) FS. History-New 9-12-01, Amended 2-28-02, 7-23-06, 3-12-08.

APPENDIX B

(Vermont)

Vermont Statutes, Title 26. Professions and Occupations, Chapter 86.

ELECTROLOGISTS

As used in this chapter:

- (1) "Director" means the director of the office of professional regulation.
- (2) "Disciplinary action" means any action taken by an administrative law officer established under subsection 129(j) of Title 3 against a certified electrologist or an applicant. It includes all sanctions of any kind, including obtaining injunctions, refusal to grant or renew certification, suspension or revocation of certification, issuing warnings and other similar sanctions.
- (3) "Electrology" means the removal of hair by electrical current using needle/probe electrode-type epilation which would include electrolysis (direct current/DC), thermolysis (alternating current/AC), or a combination of both (superimposed or sequential blend). "Electrology" includes the use by properly trained licensed electrologists of lasers approved by the United States Food and Drug Administration for electrology and as otherwise permitted by Vermont law.

(4) "Electrology office" means a facility regularly used to offer or to perform the practice of electrology.

(5) "Practice of electrology" or "practicing electrology" means engaging in the performance of electrology.

APPENDIX C

(Massachusetts)

Part I. Title XVI. PUBLIC HEALTH, Chapter 111. PUBLIC HEALTH

§ 111:5I. Laser equipment; rules and regulations; penalties for violation

The department may from time to time, after a public hearing, adopt, alter or repeal such rules and regulations relative to the use of laser systems, devices or equipment as it shall deem necessary to protect the public from the hazards of laser rays or beams, with penalties for the violation thereof not exceeding five hundred dollars for any particular offense. Such rules and regulations may require the registration of said systems, devices or equipment.

This section shall not be construed as limiting the powers of the department of labor and standards under the provisions of chapter one hundred and forty-nine relative to the prevention of accidents or injuries to employees.

(effective 6/9/2011)

APPENDIX D

(Illinois)

Sec. 20. Exemptions. This Act does not prohibit:

(1) A person licensed in this State under any other Act from engaging in the practice for which that person is licensed.

(2) The practice of electrology by a person who is employed by the United States government or any bureau, division, or agency thereof while in the discharge of the employee's official duties.

(3) The practice of electrology included in a program of study by students enrolled in schools or in refresher courses approved by the Department.

Nothing in this Act shall be construed to prevent a person who is licensed under this Act and functioning as an assistant to a person who is licensed to practice medicine in all of its branches from providing delegated services. Such delegated services may not be performed by a person while holding himself or herself out as an electrologist or in any manner that indicates that the services are part of the practice of electrology.

(Source: P.A. 96-569, eff. 8-18-09.)

(225 ILCS 412/23)

(Section scheduled to be repealed on January 1, 2014)

Sec. 23. Scope of practice.

(a) The scope of practice of an electrologist is limited

to the following:

(1) The application of an antiseptic on the area of the individual's skin to which electrology will be applied.

(2) The use of a sterile needle/probe electrode type epilation, which includes (i) electrolysis, known as direct current/DC, (ii) thermolysis, known as alternating current/AC, or (iii) a combination of both electrolysis and thermolysis, known as superimposed or sequential blend.

(b) Nothing in this Act shall be construed to authorize an electrologist to perform surgery. Services involving laser technology may only be performed if they are delegated by a physician licensed to practice medicine in all its branches consistent with Section 20 of this Act and the Medical Practice Act of 1987 and any rules promulgated thereto. An electrologist shall refer to a licensed physician any individual whose condition, at the time of evaluation or service, is determined to be beyond the scope of practice of the electrologist, such as an individual with signs of infection or bleeding.

(Source: P.A. 96-569, eff. 8-18-09.)

(225 ILCS 412/25)

APPENDIX E

(North Carolina)

§ 88A-11.1. Requirements for licensure as a laser hair practitioner; limitations on licensed laser hair practitioners.

(a) Any person seeking licensure by the Board as a laser hair practitioner shall have met the following requirements at the time the license is requested:

- (1) Be an electrologist licensed under this Chapter.
- (2) Completed a minimum 30-hour laser, light source, or pulsed-light treatment certification course approved by the Board and in accordance with rules adopted by the Board.
- (3) Be currently using or anticipate using laser, light source, or pulsed-light devices that the person has been certified by a Board-approved school to operate.

(b) When the Board determines that an applicant has met all the requirements for licensure, and has submitted the initial license fee required in G.S. 88A-9(b), the Board shall issue a license to the applicant.

(c) Each laser hair practitioner shall practice laser, light source, or pulsed-light treatments under the supervision of a physician licensed under Article 1 of Chapter 90 of the General Statutes. The physician shall be readily available, but not required to be on site when the laser, light source, or pulsed-light treatments are being performed. However, the authority to regulate laser clinicians shall remain with the Board.

(d) A laser hair practitioner shall not dispense or administer medication or provide advice regarding the use of medication, whether prescription or over-the-counter, in connection with laser, light source, or pulsed-light treatments.

(e) All laser hair practitioners shall use laser, light source, or pulsed-light devices approved by the federal Food and Drug Administration and comply with all applicable federal and State regulations, rules, and laws. Any licensed laser hair practitioner violating this subsection shall have his or her license revoked by the Board.

(f) Only a licensed physician may use laser, light source, or pulsed-light devices for ablative procedures. (2007-489, s. 6.)

APPENDIX F

(Florida)

2) The course consists of thirty (30) hours of instruction, which may include 15 hours of home-study didactic training, in the use of laser and light-based hair removal or reduction devices, including:

- (a) Biology of hair;
- (b) Laser and light-based device terminology;
- (c) Basic electricity;
- (d) Laser and light-based hair removal physics, including:
 - 1. The theory of traditional light.
 - 2. The theory of coherent light.
 - 3. The electromagnetic spectrum.
 - 4. The different types of laser and light-based hair removal devices.

5. The history of laser and light-based device development.
6. The history of medical laser and light-based device development.
7. Understanding photonic principles and how a laser and light-based device works.
8. Hair removal laser and light-based device delivery systems.

(e) Safety and precautions, including:

1. Federal and quasi-federal regulatory agencies and their roles in safety.
2. Treatment room considerations.
3. Eye safety for the operator and the patient.
4. Fire safety.

(f) Laser and light based tissue interaction, including:

1. Grothus draper law.
2. Reflection, transmission, scatter and absorption.
3. The melanin and hemoglobin absorption curve at various hair removal device wavelengths.
4. Depth of penetration and wavelength.
5. Possible effects of absorption of light energy.
6. Selective photothermolysis, including:
 - a. Wavelength.
 - b. Pulse duration.
 - c. Energy fluence.
 - d. Spot size.

(g) Sanitation;

(h) Fitzpatrick skin typing;

(i) The patient intake form;

- (j) The consultation;
- (k) Proper documentation of patient case history and consent forms;
- (l) Pre-treatment patient preparation including test spot considerations and the Nikolski sign;
- (m) Treatment contra-indications including the recognition of disease conditions of the skin;
- (n) Handpiece and spot size considerations;
- (o) Fluence setting;
- (p) Stretch technique;
- (q) Use of grid stamp;
- (r) Post-treatment procedures, including:
 1. Application of ice and medication.
 2. Instructions to patients.
- (s) Expected outcomes including erythema and edema;
- (t) Possible adverse outcomes;
- (u) Follow-up care;
- (v) The concept of using needle-type epilators to complement laser and light-based hair removal or reduction devices; and
- (w) At least five (5) hours of hands-on experience with laser and light-based devices to include hair removal or reduction from all areas of the body.

APPENDIX G

PROPOSED COURSE CURRICULUM FOR CONNECTICUT CERTIFICATION

The course consists of forty (40) hours of instruction, which may include 15 hours of home-study didactic training, in the user of laser and light-based hair removal or reduction devices, that may include the following topics:

- A. Biology of hair
- B. Laser and light-based hair removal physics, including:
 1. The theory of traditional light.
 2. The theory of coherent light.
 3. The electromagnetic spectrum
 4. The different types of laser and light-based hair removal devices.
 5. The history of laser and light-based device development
 6. Understanding photonic principles and how a light-based device works.
 7. Hair removal laser and light-based device delivery systems.
- C. Safety and precautions including:

1. Federal and quasi-federal regulatory agencies and their roles in safety.
2. Treatment room considerations
3. Eye safety for the operator and the patient.
4. Fire safety.

D. Laser and light-based tissue interaction including:

1. Grothus draper law
2. Reflection, transmission, scatter and absorption
3. The melanin and hemoglobin absorption curve at various hair removal device wavelengths.
4. Depth of penetration and wavelength.
5. Possible effects of absorption of light energy.
6. Selective photo-thermolysis including:
 - a) Wavelength
 - b) Pulse duration
 - c) Energy fluence
 - d) Spot size.
 - e) Sanitation
 - f) Fitzpatrick skin typing
 - g) The patient intake form
 - h) Consultation
 - i) Proper documentation of patient case history and consent forms.
 - j) Pre-treatment patient preparation including test spot considerations and the Nikolski sign
 - k) Treatment contra-indications including the recognition of disease conditions of the skin.
 - l) Hand-piece and spot size considerations.
 - m) Fluence setting
 - n) Stretch techniques
 - o) Use of grid stamp
 - p) Post-treatment procedures, including application of ice and after treatment care.

E. Instructions to patients:

1. Expected outcomes including erythema and edema
2. Possible adverse outcomes
3. Follow-up care
4. The concept of using needle-type epilators to complement laser or light-based hair removal or reduction devices;

F. Hands-on experience with laser and light-based devices to include hair removal and reduction from all areas of the body.

Providers Currently approved for Electrology instruction by the Connecticut Department of Health which currently offer laser hair removal training

1. Berkowitz School of Electrolysis, Inc-45 hrs
<http://www.berkowitzschool.com/>, <http://laserhairinstitute.com/>,
<http://laserhairinstitute.com/id2.html>, <http://laserhairinstitute.com/id3.html>,
2. Hollywood Institute of Beauty Careers http://hi.edu/beauty_school/laser_hair.html,