HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 329 Laser Hair Removal or Reduction
SPONSOR(S): Business & Professions Subcommittee, Rodriguez, A.M.
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	14 Y, 0 N	Gilani	McElroy
2) Business & Professions Subcommittee	15 Y, 0 N, As CS	Wright	Anstead
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The Board of Medicine (Board) under the Department of Health (DOH) currently regulates the licensing and practice of electrology, with assistance from the Electrolysis Council. “Electrology” or “electrolysis” generally means a process to permanently remove body hair using a probing device which uses electrical or heat energy to destroy the hair follicle. To obtain an electrologist license, a person must successfully complete a 120-hour training program, 200 practice hours, and a written examination.

Additional requirements apply if an electrologist uses laser or light-based devices to remove hair. The electrologist must complete a 30-hour training course in laser or light-based devices for hair removal or reduction, pass the Certified Medical Electrologist test, only use devices for which they receive training, and practice under the direct supervision of a physician.

HB 329 revises the framework for the oversight of electrology and makes conforming changes. Specifically, the bill:

- Eliminates the Electrolysis Council and makes solely the Board responsible for regulating the practice of electrology;
- Broadens the definition of electrolysis/electrology to encompass the use of laser or pulsed-light devices in permanent hair removal or reduction;
- Allows an electrologist who wishes to use laser and light-based devices to either pass of an examination from a national electrology or board-approved organization in the use of such devices, or pass a board-approved license exam in electrology and laser and light-based devices; and
- Requires electrologists who use laser and light-based devices to take at least 10 hours of continuing education on such devices as part of the current requirement to take 20 hours of CE biennially.

The bill has an insignificant, negative fiscal impact on DOH that can be absorbed within existing resources and may be offset by elimination of administrative costs associated with the Electrolysis Council. The bill has no fiscal impact on local governments.

The bill has an effective date of October 1, 2019.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Regulation of Electrology

The Florida Board of Medicine (Board) within the Department of Health (DOH) regulates the practice of electrology in the state, with input from the Electrolysis Council.[1] The Electrolysis Council is an advisory body[2] housed under the Board to assist in setting the standards of electrology practice and promulgating rules to regulate electrology.[3] The Board may delegate to the Council any duties it deems appropriate,[4] but ultimately maintains regulatory authority over the practice of electrology.[5]

Electrologists provide services to remove unwanted hair using needle-type epilators[6] or laser or light-based devices approved by the United States Food and Drug Administration (FDA) for permanent hair removal or reduction.[7]

Electrolysis

Section 478.42(5), F.S., defines "Electrolysis or electrology" as the practice of "permanent removal of hair by destroying the hair-producing cells of the skin and vascular system, using equipment and devices approved by the board which have been cleared by and registered with the FDA and that are used pursuant to protocols approved by the board." The process generally starts by inserting a probe into the hair follicle, which destroys the hair at its root with an electrical current or shortwave radio frequency, and then the loosened hair is removed with tweezers.[8] The procedure takes place in a DOH-licensed electrology facility.[9]

An electrology license is required to practice electrology in the state.[10] However, medical and osteopathic physicians can perform electrolysis and laser and light-based hair removal or reduction without an electrology license.[11] Additionally, advanced practice registered nurses (APRNs) and physician assistants (PAs) may practice laser or light-based hair removal or reduction without an electrology license if they are directly supervised[12] by a physician and conform to practice requirements set forth by the Board and applicable protocols.[13] APRNs and PAs, if they are supervised by a medical

[1] Ss. 478.43, 478.51, and 478.52, F.S.
[2] The Electrolysis Council consists of 5 Board-appointed members; 3 of whom must be actively licensed electrologists, and 2 of whom must be consumer members. Section 478.44, F.S.
[3] Ss. 478.43, 478.44, and 478.52, F.S.
[4] The Board has delegated the following powers and duties to the Electrolysis Council: approval and denial of licensure applications, approval and denial of continuing education providers and electrolysis training programs, approval and denial of AHCA exemptions pursuant to s. 435.07, F.S., the authority to accept non-disciplinary voluntary relinquishments of licensure, and the authority to notice rules for development and propose rules to the Board (the Board ultimately promulgates the rules but considers the Council's recommendations). Rule 64B8-50.003, F.A.C.
[5] s. 478.43(3), F.S.
[6] A needle-type epilator is a device intended to destroy the dermal papilla of a hair by applying electric current at the tip of a fine needle that has been inserted close to the hair shaft, under the skin, and into the dermal papilla. 21 C.F.R. § 878.5350.
[7] Florida Department of Health, Agency Analysis of 2019 HB 329, p. 2 (Jan. 17, 2019)(on file with the House Health Quality Subcommittee staff).
[8] U.S. FOOD & DRUG ADMINISTRATION, *Removing Hair Safely, Epilators: Needle, Electrolysis, and Tweezers*, https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048995.htm (last visited Feb. 11, 2019). *See also*, AMERICAN ELECTROLOGY ASSOCIATION, *How Does Electrolysis Work?* https://www.electrology.com/faqs-about-permanent-hair-removal/what-is-the-electrolysis-process.html (last visited Feb. 11, 2019).
[9] S. 478.51, F.S.
[10] S. 478.49, F.S.
[11] Ss. 458.348(2), 459.025(2), and 478.54, F.S.
[12] Onsite supervision. Rules 64B8-30.001 and 64B15-6.001, F.A.C.
[13] Ss. 458.348(2) and 459.025(2), F.S.

doctor and practice in an office at which the exclusive service being performed is laser hair removal, are exempt from the direct supervision requirement.[14]

To qualify for licensure as an electrologist, an applicant must: [15]

- Be at least 18 years old;
- Be of good moral character;
- Possess a high school diploma or equivalent;
- Not have committed acts which would constitute grounds to discipline an electrologist in Florida;
- Have completed a board-approved 120-hour electrolysis training program and 200 hours of practical application; and
- Pass a Board-approved national written exam.

Licensees must complete 20 hours of continuing education in order to renew their license every 2 years.[16]

If licensees violate the electrology practice act, they can be disciplined with penalties set forth in the physician practice act, which include: suspension, probation, fines, reprimands, refunds, and remedial education.[17] In FY 17-18, DOH received 26 complaints against electrologists, 12 of which were found legally sufficient.[18] DOH filed Administrative Complaints against 9 electrologists for violations of their practice act and imposed discipline in 4 cases.[19]

Currently, there are 1,418 actively licensed electrologists and 315 actively licensed electrology facilities in Florida.[20]

Laser Hair Removal

In addition to needle-type epilators, laser or light-based devices can be used for hair removal or reduction. Both laser and light-based devices work by producing light energy that is absorbed by melanin in the hair follicle, which causes damage to the hair, thereby reducing hair growth.[21] Specifically, laser devices produce a single, concentrated wavelength of light, and light-based devices produce a broad spectrum of light to target hair follicle melanin.[22] This is in contrast to needle-type epilators, which destroy the hair-producing cells of the skin and vascular system.

The FDA regulates laser and light-based hair removal devices as medical devices[23] but does not regulate the type of training or licensure required to use such devices, leaving that to the individual states.

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[14] S. 458.348(3)(e), F.S.
[15] S. 478.45, F.S.
[16] S. 478.43(4); R. 64B8-52.001, F.A.C. The practice act also allows renewal through a reexamination approved by the Board, but this option is not known to have ever been used. Email from Gary Landry (8505565891@vzwpix.com), Office of Legislative Planning, Florida Department of Health, March 4, 2019.
[17] ss. 478.52 and 456.072(2), F.S.
[18] Florida Department of Health, *Annual Report & Long-Range Plan*, *Fiscal Year 2017-2018*, pp. 31-36, available at: http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-1718.pdf (last visited Feb. 21, 2019).
[19] Id.
[20] FLORIDA DEPARTMENT OF HEALTH, *License Verification Portal,* https://appsmqa.doh.state.fl.us/MQASearchServices/HealthCareProviders (last visited Feb, 11, 2019).
[21] MAYO CLINIC, *Laser Hair Removal Overview*, https://www.mayoclinic.org/tests-procedures/laser-hair-removal/about/pac-20394555 (last visited Feb. 11, 2019). *See also,* ELECTROLYSIS SOCIETY OF FLORIDA, *What is the difference between the way electrolysis works and the way laser works?*, https://www.hairremovalflorida.com/blog/what-is-the-difference-between-the-way-electrolysis-works-and-the-way-laser-works (last visited Feb. 11, 2019).
[22] Id.
[23] U.S. FOOD & DRUG ADMINISTRATION, *Radiation-Emitting Products, Laser Facts*, https://www.fda.gov/Radiation-EmittingProducts/ResourcesforYouRadiationEmittingProducts/ucm252757.htm#1 (last visited Feb. 21, 2019).

States handle the practice of laser hair removal in various ways. Some states only allow a physician or someone under physician supervision to perform the procedure; some states allow an electrologist or other licensed professional to independently perform the procedure; and at least one state has no regulation, allowing anyone to perform the procedure.[24] Those states which do have laser hair removal regulations generally require the person performing the procedures to receive training or certification in the use of laser or light-based devices for laser hair removal or reduction.

In Florida, an electrologist must meet additional requirements to use laser or light-based devices to permanently remove or reduce hair.[25] Specifically, the electrologist must: [26]

- Complete a 30-hour training course in laser or light-based devices for hair removal or reduction;
- Pass the Certified Medical Electrologist test (CME test) given by the Society of Clinical and Medical Hair Removal, Inc. (SCMHR);[27]
- Use only the devices for which they have received training; and
- Operate under the direct supervision of a licensed physician trained in such procedures.

SCMHR is the national electrology organization that offers certification for use of laser and light-based devices, education programs for hair removal procedures, and membership services.[28] The Board-required CME test is $200 for members of the organization and $300 for non-members.[29] Once certified to use laser or light-based devices, licensees are not required to renew this CME certification to practice laser hair removal or renew licensure.[30]

Currently, there are approximately 220 licensed electrologists who have the required protocols to practice laser and light-based hair removal or reduction.[31]

In 2017, the Board amended its rules to establish a 320-hour combined pre-licensure training curriculum that includes training and application in both epilator and laser and light-based hair removal.[32] Additionally, the state licensure exam has been amended to encompass both electrolysis and laser hair removal.[33]

In 2018, the Board proposed rule amendments to the protocols for laser and light-based devices. These proposed rules would give electrologists an alternative to the current certification requirements and allow electrologists to use laser or light-based devices if they have completed the combined pre-licensure training program and passed the state licensure exam that now tests both electrolysis and laser hair removal modalities. These electrologists would not need to pass a nationally recognized certification exam in order to use laser or light-based devices. These rules will be effective March 14, 2019.[34]

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[24] *Use of Lasers/Delegation of Medical Functions: Board-by-Board Overview*, FEDERATION OF STATE MEDICAL BOARDS, Jan. 4, 2018, *available at:* http://www.fsmb.org/siteassets/advocacy/key-issues/laser-regulation-by-state.pdf (last visited Feb. 11, 2019). NY currently does not regulate laser hair removal.
[25] Physicians, APRNs, and PAs are exempt from these certification requirements. *Supra* notes 11, 12, 13, and 14.
[26] R. 64B8-56.002, F.A.C.
[27] As a prerequisite to the CME, one must pass the Certified Clinical Electrologist Exam, which is also offered by SCMHR. *Supra* note 7, at 3. SCMHR is designated in rule as the nationally recognized certification entity. Rule 64B8-56.002, F.A.C.
[28] THE SOCIETY FOR CLINICAL & MEDICAL HAIR REMOVAL, INC., *About Us*, https://www.scmhr.org/about/ (last visited Feb. 11, 2019). *See also* Rule 64B8-56.002(2)(b), F.A.C., identifying SCMHR as the Board-approved certification entity.
[29] THE SOCIETY FOR CLINICAL & MEDICAL HAIR REMOVAL, INC., *Certified Medical Electrologist (CME) Examination Application* https://www.scmhr.org/wp-content/uploads/2018/06/CME-App_CBT.pdf (last visited Feb. 11, 2019). Membership costs $195 annually, *Id.* at *Membership,* https://www.scmhr.org/product/membership/ (last visited Feb. 11, 2019).
[30] *Supra* note 7, at 3.
[31] *Supra* note 7.
[32] *Supra* note 7, at 3; Rule 64B8-53.002, F.A.C.
[33] Id.
[34] R. 64B8-56.002, F.A.C.; FLORIDA DEPARTMENT OF HEALTH, *Electrolysis, Laser Information,* http://www.floridahealth.gov/licensing-and-regulation/electrolysis/laser/index.html (last visited Feb. 21, 2019).

Approximately 445,000 laser hair removal procedures were performed in the United States in 2017.[35] The Bureau of Labor Statistics lists Florida as one of the top five states with the highest level of employment in the occupation of skincare specialists, which includes electrologists and laser hair removal specialists.[36] Employment of skincare specialists is expected to grow by 14 percent from 2016 to 2026.[37]

As the industry grows, so does the number of related lawsuits for related injuries. One retrospective study of malpractice lawsuits related to laser procedures over the course of a 27-year period found that laser-based litigation increased over time and hair removal procedures were the leading cause of injury in the complaints.[38] A similar study found that the rise in related lawsuits may be attributed to non-physician operators performing such procedures without physician supervision, but it also stated that a lack of adequate training by any practitioner could be dangerous.[39] While one-third of laser hair removal procedures in total are performed by a non-physician operator, seventy-five percent of the lawsuits related to laser hair removal were done by non-physician operators. Most of these cases were performed outside of a traditional medical setting.[40]

Effect of the Bill

HB 329 eliminates the Electrolysis Council to make the Board solely responsible for regulating the practice of electrology, and makes numerous conforming changes to reflect this.

The bill revises the definition of "electrolysis or electrology" to remove the specification that the hair is permanently removed or reduced by destroying the hair producing cells of the skin and vascular system. This revised definition is broad enough to encompass other manners in which hair may be permanently removed or reduced, such as through the use of laser or light-based devices.

The bill allows an electrologist who wishes to use laser and light-based devices to either pass of an examination from a national electrology or board-approved organization in the use of such devices, or pass a board-approved license exam in electrology, and laser and light-based devices.

The bill also requires electrologists who use laser and light-based devices to take at least 10 hours of continuing education on such devices as part of the current requirement to take 20 hours of CE biennially.

The bill provides an effective date of October 1, 2019.

B. SECTION DIRECTORY:

Section 1: Amends s. 478.42, F.S., relating to definitions.
Section 2: Amends s. 478.43, F.S., relating to Board of Medicine; powers and duties.
Section 3: Repeals s. 478.44, F.S., relating to the Electrolysis Council.
Section 4: Amends s. 478.45, F.S., relating to requirements for licensure.

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[35] STATISTICA, THE STATISTICS PORTAL, *Number of Laser, Light, or Energy-Based Procedures in The U.S. in 2017, by Type*, https://www.statista.com/statistics/319224/distribution-of-laser-light-energy-based-procedures-in-the-us-by-type/ (last visited Feb. 21, 2019).
[36] U.S. DEPARTMENT OF LABOR, BUREAU OF LABOR STATISTICS, *Occupational Employment and Wages, May 2017, Skincare Specialists,* https://www.bls.gov/oes/current/oes395094.htm#st (last visited Feb. 21, 2019).
[37] U.S. DEPARTMENT OF LABOR, BUREAU OF LABOR STATISTICS, *Skincare Specialists, Job Outlook,* https://www.bls.gov/ooh/personal-care-and-service/skincare-specialists.htm#tab-6 (last visited Feb. 21, 2019).
[38] H. Ray Jalian, MD, et al.; *Common Causes of Injury and Legal Action in Laser Surgery Causes*, 149 JAMA DERMATOLOGY 188 (2013), available at: https://jamanetwork.com/journals/jamadermatology/fullarticle/1654904 (last visited Feb, 21, 2019). From 1985 to 2012, 63 of the 174 laser-related malpractice cases found were related to laser hair removal procedures, with a peak in 2011 but an overall increase over time.
[39] H. Ray Jalian, MD, et al., *Increased Risk of Litigation Associated with Laser Surgery by Nonphysician Operators*, 150 JAMA DERMATOLOGY 410 (2014), available at: https://jamanetwork.com/journals/jamadermatology/fullarticle/1754984 (last visited Feb. 21, 2019).
[40] Id. Approximately 70% of procedures were performed in a medical spa setting rather than a health care practice.

Section 5: Amends s. 478.49, F.S., relating to required licensure.
Section 6: Amends s. 478.50, F.S., relating to renewal of licensure.
Section 7: Amends s. 478.52, F.S., relating to disciplinary proceedings.
Section 8: Amends s. 478.53, F.S., relating to penalties for violations.
Section 9: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH may incur costs related to rulemaking to remove the Electrolysis Council's involvement in electrology practice regulation, which can be absorbed within existing resources,[41] and to amend rules related to requirements for electrologists to use laser or light-based modalities.

   Additionally, DOH may experience cost savings to the extent that it will no longer facilitate activities and quarterly meetings of the Electrolysis Council and will instead be able to consolidate these items into the Board's activities and meetings.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

To the extent that electrologists want to use laser and pulsed-light devices, the bill provides options when choosing a pathway to use such devices.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

[41] *Supra* note 7, at 5.

DOH has sufficient rulemaking authority to implement the changes under the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 6, 2019, the Business & Professions Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Adds options that allow an electrologist that uses laser and light-based devices to either pass an examination from a national electrology or board-approved organization in the use of such devices, or pass a board-approved license exam in electrology, and laser and light-based devices.
- Provides that electrologists who use laser and light-based devices must take at least 10 hours of continuing education on such devices as part of the current requirement to take 20 hours of CE biennially.

This analysis is drafted to the committee substitute as passed by the Business & Professions subcommittee.