DEPARTMENT OF HEALTH ELECTROLYSIS COUNCIL GENERAL BUSINESS MEETING May 16, 2016 2:00 p.m. EST CONFERENCE CALL 1-888-670-3525

When prompted, enter the following conference code number: **7811783909,** followed by the # sign.

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the council's website.

Members Present

Ms. Jolynn Greenhalgh, DNP, ARNP, RE, Chair Ms. Lina Grillo, RE Ms. Nilsa Lapeyrouse, RE Ms. Sarah Gray, Esquire Ms. Erin Wiedemer, PMP

Staff Present

Allen Hall, Executive Director Anna King, Program Administrator Kimberly Thomas, Regulatory Specialist II Deb Boutwell, Regulatory Specialist II

Assistant Attorney General

Lynette Norr, Esquire

Additional Persons Present

Jon Pellet, Esquire Judy Adams, RE Sandi Allen, Esquire Teresa Petricca, Former AEA Pres./Exec.Dir.

The minutes reflect the actual order in which the agenda items were considered during the meeting.

2:00 p.m. Call to Order – General Business Meeting

ADMINISTRATIVE PROCEEDINGS

320-HOUR ELECTROLYSIS TRAINING SCHOOL APPLICATION

2. ASM Beauty Academy

ASM was not present and not represented by legal counsel.

Following discussion, Ms. Greenhalgh moved to approve ASM Beauty Academy's 320-Hour Electrolysis Training School application. Ms. Grillo seconded the motion, which carried 5/0.

May 16, 2016 Electrolysis Council General Business Meeting

APPLICANT CERTIFICATION LIST

3. Examination Applicants

The April 28, 2016 Examination Candidate Ratification List was presented to the Council for approval.

Ms. Greenhalgh moved to ratify the revised list of examination candidates. Ms. Lapeyrouse seconded the motion, which carried 5/0.

ADDITIONAL ADMINISTRATIVE ITEMS

16. INDIVIDUAL CONSIDERATION: MEGHAN KING, EXAM APPLICANT

Ms. King was present and not represented by legal counsel.

Ms. King was before the Council for review of her application for licensure by exam. Following discussion, Ms. Greenhalgh moved to approve the application. Ms. Lapeyrouse seconded the motion, which carried 5/0.

17. REVIEW OF 320-HOUR ELECTROLYSIS TRAINING PROGRAM INSTRUCTOR: HOLLYWOOD INSTITUTE (HOLLYWOOD CAMPUS)

Mr. Neal Heller, Esquire, was present on behalf of Hollywood Institute.

Mr. Heller stated that Ms. Monika Kardos is no longer an instructor at Hollywood Institute. Mr. Heller indicated that Ms. Lucky Syms is currently the instructor and therefore no action was required.

Mr. Hall stated that if Ms. Kardos is considered for an instructional position in the future in the electrolysis training program in the future, Hollywood Institute must first notify the Council.

19. INDIVIDUAL CONSIDERATION: AUDREY SASSOON, EXAM APPLICANT

Ms. Sassoon was present and not represented by legal counsel.

Ms. Sassoon was before the Council for review of her application for licensure by exam.

Following discussion, Ms. Greenhalgh moved to approve the application. Ms. Lapeyrouse seconded the motion, which carried 5/0.

18. REVIEW OF COMBINED TRAINING PROGRAM: BOCA BEAUTY ACADEMY

Ms. Lisa Ring was present and not represented by legal counsel.

Ms. Ring corrected all errors and separated the Electrolysis Program from the Paramedical Esthetician Program in documentation submitted to the Council for review.

Ms. Greenhalgh moved to approve the Electrolysis portion of the Paramedical Esthetician Program. Ms. Grillo seconded the motion, which carried 5/0.

ANTI-TRUST PRESENTATION

1. Lynette Norr, Assistant Attorney General

Ms. Norr provided a PowerPoint presentation to the Board regarding Anti-Trust. The presentation included the following:

- Antitrust Overview
- Background of the North Caroline State Dental Board Case
- Summary of Supreme Court's February 25th Ruling
- Recent Federal Trade Commission Staff Guidelines
- Potential Implications for Regulatory Boards
- Pending Cases Against State Regulatory Boards

Ms. Norr responded to questions throughout the presentation.

RULES REVIEW AND DEVELOPMENT

4. Rule Discussion – Lynette Norr, Assistant Attorney General

Ms. Norr provided drafts of several rules for final review and approval to be presented to the Board of Medicine at its June 2016 meeting.

• 64B8-51.006 Rule Governing Licensure and Inspection of Electrology Facilities

Ms. Norr presented for discussion during the meeting revisions to Paragraphs (3)(c), (5)(c), (6)(a) and (8) of the rule. The full text reviewed by the Council is as presented below.

64B8-51.006 Rule Governing Licensure and Inspection of Electrology Facilities.

(1) Definitions. An electrology facility is that portion of any establishment or place wherein electrolysis is performed. An electrology facility may be part of a residence.

(2) Electrology Facility Licensure.

(a) No one may operate an electrology facility without a license to do so from the Department of Health. The owner of an electrology facility is required to obtain a license for the electrology facility. However, physicians licensed under Chapter 458 or 459, F.S., are not required to obtain an electrology facility license and electrologists employed by physicians licensed under Chapter 458 or 459, F.S., are not required to obtain an electrology facility license.

(b) To obtain the license, the applicant shall provide information to the Department as required by this rule on a form provided by the Department and approved and incorporated herein by reference by the Board as Form DH-MQA 1213, entitled Licensure," "Application for Electrolysis Facility effective 3/13, which can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-02754 or the Department at The Florida Department of Health, Electrolysis Council, Bald Cypress Way, Bin #C05, Tallahassee, Florida 32399-3256. The applicant must pay a \$100 application fee, which is nonrefundable, \$100 inspection fee, \$100 licensure fee and a \$5.00 unlicensed activity fee.

(3) Electrology Facility Safety and Sanitary Requirements. <u>Paragraph (a) of this subsection applies to all electrology facilities</u> <u>regardless of the modalities used</u>. <u>Paragraph (b) of this rule applies to electrology facilities where epilators are used</u>. <u>Paragraph (c) of this rule applies to electrology facilities where laser or light-based equipment is used</u>.

(a) Listed below are requirements to be followed, and materials and equipment to be available at each electrology facility

where epilators or lasers/light-based equipment is used. An electrology facility shall be clean, sanitary and well-lit. It shall also allow for circulation of air sufficient to eliminate odors.

1. Any room wherein electrolysis is performed shall have four fixed, permanent walls at least six feet tall from the floor and shall have doors capable of being locked. Permanent walls means a vertical continuous structure of wood, plaster, masonry, or other similar building material, which is physically connected to the electrology facility floor. At the time of service, each client shall be protected from view of the public, and any other clients at the facility. This requirement shall not apply to electrology facilities which are located in an electrolysis training facility so long as the unwalled area where electrolysis is performed is used for instructional purposes only. when electrolysis training is undertaken in accordance with a training program approved by the Electrolysis Council.

2. There shall be a <u>toilet and</u> sink with hot and cold running water <u>available to</u> within the electrology facility. This sink may also serve as the sink in the toilet and lavatory facilities required under paragraph (3)(c) of this rule. The toilet and sink shall be kept clean and in working order when the electrology facility is open for business.

(b) The following documents shall be displayed in an area that is visible to the general public entering the facility:

1. The electrology facility license.

2. The current license of the electrologist.

3. The most recent inspection sheet from the Department of Health.

4. A current copy of Rule 64B8 51.006, F.A.C.

(c) Toilet and Lavatory Requirements. Each electrology facility shall provide, on the premises or in the same building, a separate room containing toilet and lavatory facilities which shall have at least one toilet and one sink with running water, and shall be equipped with toilet tissue, soap dispenser with soap or other hand cleaning material, disposable towels or wall mounted electric blow dryer, and a waste receptacle. The toilet and lavatory facilities and all fixtures and components shall be clean, in good repair, well-lighted and adequately ventilated to remove objectionable odors.

(d) No animals shall be allowed to enter or be in the room wherein electrolysis is performed except those trained to assist the hearing impaired, visually impaired, or the physically impaired.

(e) The electroogy facility shall have the following equipment:

-1. An FDA registered needle-type epilation device in working order;

2. Clean and sterile needles/probes and forceps/tweezers;

3. Needle holder tips;

<u>3.-4.</u> Electrolysis shall be conducted on A <u>a</u> treatment table or treatment chair with a non-porous surface capable of being disinfected;

4. The following supplies and equipment shall always be available at the electrology facility:

a.5. Disposable paper drapes or sanitary cloth drapes stored in a closed container or compartment;

<u>b.</u> Sanitary waste receptacles for the disposal of used gloves, paper supplies, cotton balls, and other noninfectious items;

c.7. Single use, disposable towels;

8. A sharps container for disposal of used needles/probes;

d.9. A treatment lamp or magnifier lamp capable of being cleaned with disinfectant;

e.10. A magnifying device which shall be a magnifier lamp, optical loupe or microscope capable of being cleaned and disinfected;

<u>f.11.</u> Tuberculocidal hospital grade disinfectant registered by the Environmental Protection Agency, household bleach or wiping cloths pre-saturated with disinfectant for wiping non-porous surfaces;

12. If eye shields are used, eye shields capable of being cleaned with disinfectant;

13. Covered containers for needles/probes and forceps/tweezers which containers are capable of being cleaned and sterilized:

<u>g.</u>14. Betadine, 3% U.S. Pharmaceutical grade hydrogen peroxide, or 70% isopropyl alcohol, or wrapped single use wipes saturated with 70% isopropyl alcohol;

h.15. Clean, non-sterile materials such as cotton balls, cotton strips, cotton swabs, gauze pads, and gauze strips;

<u>i.16</u>. If cloth towels are used, they shall be laundered and sanitized <u>cleaned prior to use on each client and which are</u> stored in a closed container or compartment, and there shall be a covered sanitary container for holding used cloth towels; <u>Used</u> <u>cloths shall be kept in a separate closed container;</u>

17. A sterilizer which shall be either an autoclave or a dry heat sterilizer, and color change indicators for use with either sterilizer. The endodontic dry heat "glass bead sterilizer" shall not be used for instrument sterilization;

18. Unless the facility is new, monthly records of sterilizer biological test monitoring which shall be made available to the Department upon request;

j. 19. A holding container for soaking and cleaning contaminated instruments; and

k.20. Non-sterile disposable examination gloves.

(f) An appointment book shall be maintained and kept on the electrology facility premises which lists the name of each

person who has received electrolysis treatment.

(g) In electrology facilities wherein laser equipment is used for hair removal, the following shall be provided:

(b) In addition to those specified in paragraph (3)(a), the requirements to be followed, and materials and equipment to be available at each electrology facility where epilators are used are listed below.

1. An FDA registered needle-type epilation device in working order;

2. Clean and sterile needles/probes and forceps/tweezers;

3. Needle holder tips;

4. A sharps container for disposal of used needles/probes;

5. Covered containers for needles/probes and forceps/tweezers which containers are capable of being cleaned and sterilized;

<u>6.</u> <u>A sterilizer which shall be either an autoclave or a dry heat sterilizer, and color change indicators for use with either sterilizer. The endodontic dry heat "glass bead sterilizer" shall not be used for instrument sterilization; and,</u>

7. Unless the facility is new, quarterly records of sterilizer biological test monitoring which shall be made available to the Department upon request;

(f) An appointment book shall be maintained and kept on the electrology facility premises which lists the name of each person who has received electrolysis treatment.

(c) (g) In addition to those specified in paragraph (3)(a), the requirements to be followed, and materials and equipment to be available at each electrology facilities facility wherein laser or light-based equipment is used for hair removal, the following equipment shall be provided are listed below:

1. Proof of certification of 30 hours of continuing education in laser hair removal for all electrologists using laser equipment in the facility.

2. For all electrologists using laser or light-based equipment in the facility, pProof of having passed the Society for Clinical and Medical Hair Removal test for certification as a Certified Medical Electrologist, or proof of having passed a test for an equivalent certification as approved by the Council-for all electrologists using laser or light based equipment in the facility.

3. For devices required to be registered, proof of registration for each laser or light-based device in use at the facility as required by Section 501.122, F.S.

4. Written designation of laser safety officer.

5. A room or rooms specifically designated for use of the laser or light-based equipment which is where all use of such equipment shall take place.

<u>6.5.</u> Sign on door of laser room identifying when laser or light-based equipment is in use.

<u>7.6.</u> Lock on door of laser room.

8.7. Protective eyewear capable of being cleaned and disinfected, shall be used by for all persons in laser room during operation of laser or light-based equipment.

<u>9.8.</u> Fire extinguisher in vicinity of laser room.

<u>10.9.</u> Cold water and ice.

<u>11.10.</u> The written protocols required by paragraph 64B8-56.002(4)(a), F.A.C.

(4) The following documents shall be available in each electrology facility displayed in an area that is visible to the general public entering the facility :

(a) The electrology facility license which shall be visible to the public;

(b) The current license of the electrologist which shall be visible to the public;

(c) The most recent inspection sheet from the Department of Health;

(d) <u>A current copy of Rule 64B8-51.006, F.A.C.; and,</u>

(e) <u>An appointment book shall be maintained and kept on the electrology facility premises which lists the name of each person who has received electrolysis treatment</u>. The appointment book shall be maintained for four (4) years.

(5) (4) Inspections. The Department shall inspect all electrology facilities in the following manner:

(a) All licensed facilities shall be inspected once per biennium.

(b) All facilities applying for initial licensure shall be inspected prior to licensure.

***(c) When an existing electrology facility adds a modality, either epilator or laser/light-based equipment, or switches from one of those modalities to the other, an inspection shall be conducted to determine whether the facility has properly registered equipment and the proper safety and sanitary equipment and materials. The electrology facility shall notify the Department of the new modality by submitting to the Executive Director of the Electrolysis Council the Application for Inspection for Adding or Switching to a New Electrology Modality provided by the Council and approved and incorporated herein by reference by the Board as Form DH5008-MQA-09/2015, which can be accessed through http://www.flrules.org/Gateway/reference.asp?No=Ref-

or http://www.floridahealth.gov/licensing-and-regulation/electrolysis/. The facility must pass an inspection prior to implementing the new modality.***

(6) (5) Transfer of Ownership or Location of the Electrology Facility.

***(a) No license for an electrology facility may be transferred from the name of the original licensee to another. If a facility

is sold, the new owner must apply to the Department for licensure and no electrolysis services may be performed in the facility after the sale until the new owner has received the required license from the Department. A person purchasing an electrology facility may apply to the Department for licensure prior to the date of purchase.***

(b) An electrology facility license may be transferred from one location to another only upon approval by the Department which approval shall be granted upon compliance with all requirements set out below in subparagraphs 1. through 3. Only the licenses for electrology facilities which have passed inspection at the original location are eligible for transfer to another location. In order to begin practice at the new location, the electrology facility license holder must first perform all of the following procedures:

1. File a completed application for transfer prior to the date of the transfer on forms prescribed by the Department, as referenced in paragraph (2)(b) of this rule, which application must be processed by the Council office;

2. Surrender the current license with the application; and

3. Pay \$100 to have the new location inspected to determine compliance with Rule 64B8-51.006, F.A.C. The electrology facility license holder transferring the license shall be permitted to perform electrolysis in the new facility, only after the application has been processed by the Council office and notification provided to the licensee, prior to inspection for a period of 60 days commencing with the first day electrolysis is performed in the new facility. The required inspection must be performed within the 60 day period or electrolysis services must cease until the inspection is performed.

(7)(6) Renewal of Facility Licensure. Facility licensure shall be renewed at the end of each biennium prescribed by the Department. The licensee shall receive ninety (90) days notice of the need to renew the facility license. The notice shall be sent to the licensee at the last known address of the facility. Failure to receive the notice will not excuse the licensee from the requirement to renew the facility license, and failure to renew shall result in the license becoming delinquent. If the delinquent licensee does not apply for renewal of the license within six months of the license becoming delinquent, the license shall become null and any subsequent licensure shall be as a result of applying and meeting all requirements for new licensure. A facility may not operate without a license. To timely renew the facility license, including the six month "grace period" provided for, the licensee must pay the renewal fee of \$100 and the inspection fee of \$100.

(8)(7) No license for operation of an electrology facility may be transferred from the name of the licensee to the name of another person. If a facility is sold, the new owner must apply to the Department for licensure and no electrolysis services may be performed in the facility after the sale until the new owner has received the required license from the Department. A person purchasing an electrology facility may apply to the Department for licensure prior to the date of purchase.

Rulemaking Authority 456.037, 478.43(1), (4), 478.51(3) FS. Law Implemented 456.037(2), (3), (5), 456.0635, 478.49, 478.51 FS. History–New 11-16-93, Formerly 61F6-76.006, Amended 5-11-95, 6-26-96, Formerly 59R-51.006, Amended 12-23-97, 12-22-98, 2-17-00, 3-25-01, 4-8-02, 6-16-03, 7-29-10, 6-19-13, 12-25-14, _____.

Following discussion, Ms. Greenhalgh moved to approve the language as presented. Ms. Lapeyrouse seconded the motion, which carried 5/0.

Ms. Greenhalgh moved that the proposed language would not have an adverse impact on small business nor have an economic impact on government or any other entity in excess of \$200,000 within one year of the rule being implemented. Ms. Lapeyrouse seconded the motion, which carried 5/0.

64B8-52.004 Requirements for Approval of Training Courses for Laser and Light-Based Hair Removal or Reduction

Ms. Norr presented for discussion during the meeting revisions to Paragraph (3) of the rule. The changes follow the proposed revisions to Rule 64B8-51.006(3)(c)2., F.A.C. The full text reviewed by the Council is as presented below.

64B8-52.004 Requirements for Approval of Training Courses for Laser and Light-Based Hair Removal or Reduction. The Electrolysis Council will approve laser and light-based hair removal or reduction continuing education training courses upon application if the following requirements are met:

(1) Continuing education providers seeking initial approval by the Council shall pay a fee of \$250, and shall complete and submit to the Council the application form entitled "Application for Laser and Light Based Hair Removal or Reduction Continuing Education Provider", form DOH/MQA/EO/LASER/CEU/07/23/01, which is herby incorporated by reference and became effective July 23, 2001, copies of which may be obtained from the Council office at 4052 Bald Cypress Way, BIN C-05, Tallahassee, Florida

32399-3255. Continuing education providers seeking renewal of provider status shall also pay a \$250 fee each biennium. To receive Council approval, a continuing education program:

(a) Should be submitted for the Council's approval not less than 60 days nor more than 360 days prior to the date the offering is scheduled;

(b) Shall have its sponsor submit to the Council at least the following:

1. A statement of the educational goals and objectives of the program;

2. A detailed course outline or syllabus, including such items as method of instruction, testing materials, if any;

3. A current curriculum vitae of the course instructor(s);

4. The procedure to be used for recording attendance of those attendees seeking to apply for continuing education credit and the procedure for certification by the course's registrar of attendance;

5. A sample certificate of completion; and

6. A copy of the electrology facility license and the most recent Department of Health inspection sheet from the location where the continuing education training course is offered demonstrating compliance with paragraph 64B8-51.006(3)(g), F.A.C.

(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. Grot<u>t</u>hus<u>s-D</u>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;

(I) 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.

(3) The instructors of each laser and light-based hair removal course shall have one year of <u>experience using laser or</u> <u>light-based devices for hair removal after having passed the Society for Clinical and Medical Hair Removal test for certification</u> as <u>a</u> Certified Medical Electrologist, <u>or after having passed a test for an equivalent certification as approved by the Councilpost-</u> certification experience. Verifiable documentation of this experience must be submitted to the Council with the application. <u>Rulemaking</u><u>Specific</u> Authority 456.025(7), 478.43(<u>1), (4)</u> FS. Law Implemented 456.025(7), 478.42(5), 478.43(3), 478.50 FS. History–New 10-3-00, Amended 12-24-01, 12-26-02, 8-17-04, 7-3-06, 2-18-09, _____.

During the discussion, Mr. Jon Pellet, Esq., questioned the Council's statutory authority to propose changes to the instructors' qualifications.

The Council Chair allowed for a break at 3:29 p.m. to allow Ms. Norr the opportunity to review and respond to this inquiry.

The meeting reconvened at 3:34 p.m. at which time Ms. Norr indicated she would research further in preparation to discuss the Council's authority for these changes when the rule is considered at the June 2016 Board of Medicine meeting.

Ms. Greenhalgh moved to approve the proposed rule language as presented. Ms. Lapeyrouse seconded the motion, which carried 5/0.

Ms. Greenhalgh moved that the proposed language would not have an adverse impact on small business nor have an economic impact on government or any other entity in excess of \$200,000 within one year of the rule being implemented. Ms. Lapeyrouse seconded the motion, which carried 5/0.

• 64B8-55.002 Citations

Ms. Norr presented for discussion during the meeting revisions to Paragraph (5)(I) of the rule. The changes follow the proposed language in Rule 64B8-51.006(3)(c)2., F.A.C.

(5) The Board designates the following as electrology citations violations in laser or light based hair removal. Failure to have:

 (I) Proof of <u>having passed the test for</u> certification as <u>a</u> Certified Medical Electrologist for all <u>persons</u> <u>electrologists</u> <u>who uses</u> <u>using</u> laser <u>or light-based</u> equipment in the facility<u>who are not exempt and</u> <u>are licensed electrologists</u>.
(64B8-56.002(2)(b), F.A.C.) First time violation \$500, Subsequent violation \$1,000.

<u>Rulemaking</u>Specific Authority 456.077(1), (2) FS. Law Implemented456.072(3)(b), 456.077(1), (2), 478.51, 478.52 FS. History– New 11-16-93, Formerly 61F6-80.002, Amended 1-2-95, Formerly 59R-55.002, Amended 11-13-97, 10-12-98, 2-11-01, 2-20-02, 11-12-02, 7-16-03, 2-12-07, ______.

Ms. Greenhalgh moved to approve the proposed rule language. Ms. Lapeyrouse seconded the motion, which carried 5/0.

Ms. Greenhalgh moved that the proposed language would not have an adverse impact on small business nor have an economic impact on government or any other entity in excess of \$200,000 within one year of the rule being implemented. Ms. Grillo seconded the motion, which carried 5/0.

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

Ms. Norr presented for discussion during the meeting revisions to Paragraph (2)(b) of the rule. The changes follow the proposed language in Rule 64B8-51.006(3)(c)2., F.A.C. The full text reviewed by the Council is as presented below.

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 subsections 64B8-52.004(2) and (3), F.A.C.;

(b) Have been certified passed the Society for Clinical and Medical Hair Removal test for certification as a Certified Medical Electrologist, or proof of having passed a test for an equivalent certification as approved by the Council 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. 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.

(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.

Rulemaking 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, 11-4-14,

Ms. Greenhalgh moved to approve the proposed rule language. Ms. Lapeyrouse seconded the motion, which carried 5/0.

Ms. Greenhalgh moved that the proposed language would not have an adverse impact on small business nor have an economic impact on government or any other entity in excess of \$200,000 within one year of the rule being implemented. Ms. Lapeyrouse seconded the motion, which carried 5/0.

64B8-53.001 **Requirements for Electrolysis Training Programs Approved** by the Board

Ms. Norr presented for discussion the last draft of revisions to the rule discussed by the Council at a prior meeting. In particular, the Council considered whether it would like to allow for distance learning as an option for training programs. The full text of the language presented is as follows below.

64B8-53.001 General Requirements for Pre-licensure Electrolysis Training Programs Approved by the Board. An pre-licensure electrolysis training program must demonstrate that it will comply with the following general requirements in order to be approved by the Council. Board for pre-licensure training if the following requirements are met:

(1) The electrolysis training program is licensed by the Commission for Independent Education and the license is a current, unencumbered provisional, regular or biennial license issued pursuant to Sections 1005.31-.38, F.S.

(a) (2) Electrolysis training programs intended to train individuals to practice in Florida must provide the Electrolysis Council copies of all documents submitted to the Department of Education for initial approval and renewal by the Commission for Independent Education. Failure to provide these materials to the Council shall result in a denial or revocation of program approval by the Council.

(b) (3) No home study or correspondence school or course will be considered in assessing an applicant's qualifications for licensure. Credit shall only be awarded for time spent in the classroom or clinic in the physical presence of an instructor.

(4) The content of the training program must meet the minimum curriculum standards set forth in section 64B8-53.002, F.A.C. The training program must provide the equipment listed in section 64B8-53.003. The training program shall be located in a electrology facility licensed under Rule 64B8-51.006, F.A.C. An electrolysis training program must meet the requirements for combining epilator, laser and light-based training contained by the rules in Chapter 64B6-53, F.A.C., within one year after all rules in the chapter become effective.

(5) Electrolysis training programs shall be strictly limited to training in hair removal and shall not include extemporary procedures licensed by any other Florida Board. Waxing and treatment of spider veins are two examples of such extemporary procedures.

(6) All students in the clinical application phase of an electrolysis training program, as described in Rule 64B8-53.002(2), shall have access to the equipment needed for the procedure being taught.

(7) An electrolysis training program in another state or jurisdiction which does not license the practice of electrolysis shall be an approved electrolysis training program if it meets requirements substantially equivalent to those in Ch. 64B8-53, F.A.C. (8) Students shall not be admitted to the training program until it is approved by the Council.

(2) Applicants shall complete and submit to the Council the application entitled "New Facility or New Ownership Application for Electrology Facility Licensure", form DOH/MQA/EP APP/REV-9/99, which is hereby incorporated by reference, copies of which may be obtained from the Council Office at 4052 Bald Cypress Way, BIN C05, Tallahassee, FL 32399. Approval by the Council is necessary before students are admitted.

(3) (9) The facility where initial pre-licensure training is offered shall submit to the Council at least the following:

(a) A statement of the educational goals and objectives of the program;

(b) A detailed course outline or syllabus, including method of instruction, and testing materials;

(c) A current curriculum vitae of the course instructor(s);

(d) A sample certificate or diploma which states the number of classroom hours completed and the number of clinical hours completed. includes the following which shall be filled in by the facility at the time of graduation:

	0	, ,	0	
Academic Hours		Traditional Classroom		Non-Traditional Classroom

Per subsection 64B8-53.002(1), F.A.C. Successfully Completed **Clinical Hours** Per subsection 64B8 53.002(2), F.A.C.

Traditional Classroom

Non-Traditional Classroom

Successfully Completed

(e) A copy of the electrology facility license and the most recent Department of Health inspection sheet from the location where the training courses are to be offered demonstrating compliance with Rule 64B8-51.006, F.A.C.

(f) Proof of current, unencumbered licensure by the Commission for Independent Education, pursuant to Chapter 1005, F.S. Failure to maintain that license in good standing shall result in the loss of Council approval of the Program.

(g) Provide a copy of the application form submitted by students which shall include the following Notice in bold type no smaller than 14 points:

"Notice from the Florida Electrolysis Council Applicants for an Electrolysis License in the State of Florida are required to have completed a specifically outlined course of academic and clinical studies. Those studies must have been taken in a classroom setting in the physical presence of the instructor. Only such classroom education will be considered adequate for licensure. No credit shall be awarded applicants for home study, correspondence, or other distance education.

I confirm that I have read and understand the foregoing notice.

(4) The content of the program must include the curriculum standards set forth in subsections 64B8 53.002(1) and (2), F.A.C. All curricula must harmonize with and not be contrary to the following statements:

(a) The procedures to be used for electrolysis involve the insertion of a sterile needle electrode into the hair follicle(s) of prepared skin. After the application of the selected current, the treated hair(s) is (are) removed with sterile forceps. After treatment is complete, the treated area of the skin is given post treatment care.

(b) Electrolysis training programs shall be limited to training in the universally accepted procedures of electrolysis and shall not include extemporary procedures licensed by any other Florida Board. One example of such an extemporary procedure would be waxing the treated area after electrolysis. A Cosmetology license is required for certain types of waxing. A second example would be the intentional treatment of telangiectasis (spider veins) with the epilator. This type of vascular surgery may only be performed by a Florida licensed physician.

(5) Only needle-type epilators and FDA cleared laser and light-based devices shall be used in electrolysis training programs.

(6) All students in the clinical application phase of an electrolysis training program shall have access to a full work station consisting of an epilator, treatment table, stool, and supplies. During the clinical application phase of instruction in an electrolysis training program, there shall be only one student assigned to each work station.

(7) Each facility where electrolysis training programs are offered must meet the curriculum standards in Rule 64B8 53.002, F.A.C., and have the equipment required by Rule 64B8-53.003, F.A.C.

(8) Each facility where electrolysis training programs are offered must be licensed as an electrology facility pursuant to Rule 64B8 51.006. F.A.C.

(9) An electrolysis training program in another state or jurisdiction which does not license the practice of electrolysis shall be an approved electrolysis training program if it meets requirements substantially equivalent to those in subsections 64B8-53.001(1) and (2), F.A.C.

RulemakingSpecific Authority 478.43(1), (4), 478.50(4)(b) FS. Law Implemented 478.43(4), 478.45(1)(e), 478.50(4)(b) FS. History-New 9-29-93, Formerly 61F6-78.001, Amended 6-19-96, Formerly 59R-53.001, Amended 11-13-97, 2-15-07.

Ms. Judy Adams, RE, addressed the Council during the discussion.

Following discussion regarding potential options for distance learning, Ms. Greenhalgh moved to approve the following proposed change to Paragraph (3):

(3) The didactic portion of the required training may include online and home study courses.

Ms. Lapeyrouse seconded the motion, which carried 5/0.

Ms. Greenhalgh also moved to approved changes to update the Electrologist licensure application form DH-MQA 1164 to remove any references to a home study restriction. The form

Date" Student Signature

is incorporated in Rule 64B8-51.001 (1), F.A.C. Ms. Grillo seconded the motion, which carried 5/0.

Ms. Greenhalgh moved that the proposed language for Rules 64B8-53.001(3), F.A.C. and 64B8-51.001, F.A.C., would not have an adverse impact on small business nor have an economic impact on government or any other entity in excess of \$200,000 within one year of the rule being implemented. Ms. Grillo seconded the motion, which carried 5/0.

64B8-53.002 Curriculum Standards for Electrolysis Training Programs •

Ms. Norr presented the draft language below for review by the Council in light of the Rules and Legislative Committee of the Board of Medicine's suggestion that the Council consider increasing the number of hours to more closely approach the 600 hour requirements of other states.

64B8-53.002 Curriculum Standards for Electrolysis Training Programs.	
In order to be approved by the Board, an electrolysis training program must meet the	e following curriculum standard
Academic instruction to be set out in school catalog.	Hours
(a) Introduction to electrolysis techniques through Galvanic, Thermolysis	15
and Blend, <u>and laser and light based modalities,</u> history of permanent hair	
removal, general treatment procedures	
(b) Principles of electricity, epilator functions, and adjustments.	5
(c) Laser and light-based hair removal physics	<u>5</u>
(d) Laser Safety and precautions	<u>5</u>
(e) Integumentary System (skin and appendages).	10 <u>6</u>
(f) Circulatory (blood and lymph) and nervous system.	10 <u>6</u>
(g) Endocrine system, including related diseases.	10 <u>6</u>
(h) Biology of hair growth.	<u>10</u>
(i) Skin assessment, including <u>skin</u> type s ing, effects of specific current	
all modalities, effects of temporary removal.	10 <u>20</u>
(j) Study of blood-borne pathogens with emphasis on hepatitis (all types),	10 <u>5</u>
and HIV/AIDS.	
(k) Microbiology of the skin (flora and fauna), sanitation and safety	10 <u>7</u>
procedures including demonstrations in accordance with Rule 64B8-56.001,	
F.A.C.	
(I) Clinic and office management, communications, professional ethics,	10 <u>5</u>
bookkeeping, and patient management.	
(m) Study of Chapter 64B8, F.A.C., as it relates to electrolysis, Chapter	10 <u>5</u>
478, F.S., and Chapter 456, Part II, F.S.	
(n) Consultations including medical history, contraindications, complications	5 <u>20</u>
Subtotal	120 hours
(2) Clinical Application	Hours
(a) Coordination skills with probe holder and forceps.	5
(b) Insertions	15
(c) Sanitation/Sterilization Procedures	10
(d) Hands on Equipment Instruction (Electrolysis Laser and Light-based)	5 <u>15</u>
(e) Hands on Equipment Instruction (Thermolysis)	5 <u>10</u>
(f) Hands on Equipment Instruction (Blend and Galvanic)	5 <u>10</u>
(g) Client Pre/Post Treatment	5 <u>10</u>
(h) Client Assessment	10 <u>15</u>
(i) General Treatment Procedures for all modalities	105 <u>80</u>
(j) Consultations	15
(k) Visuals/Library	10 <u>5</u>

64B8-53.002 Curriculum Standards for Electrolysis Training Programs.

(I) Review/Exam Preparation	10
Subtotal	200
Total	320 hours

<u>Rulemaking</u>Specific Authority 478.43(4), 478.50(4)(b) FS. Law Implemented 478.43(4), 478.45(1)(e), 478.50(4)(b) FS. History–New 9-29-93, Formerly 61F6-78.002, 59R-53.002, Amended 11-13-97.

Ms. Judy Adams, RE, and Mr. Jon Pellett, Esq., addressed the Council during the discussion.

After further discussion, the Council determined there was nothing to suggest a need to increase the hours of the training program. At Ms. Norr's request, the Council offered the following reasons in support of not increasing the hours:

- the training currently consists of 5 full-time weeks of instruction in insertion and handling the laser;
- the Council is unaware of any existing major disciplinary issues indicating the need for additional training;
- o increasing the number of hours would significantly increase the cost to applicants; and
- many states have set their training curriculum requirements at 600 hours or greater simply to allow students to qualify for payment of training via federal grants versus a true need for additional hours of training.

• 64B8-53.003 Required Equipment for Electrolysis Training Programs

The Council reviewed draft language approved at a prior meeting and determined it should be presented to the Board of Medicine with no additional changes. The full text of the proposed language is provided below.

64B8-53.003 Required Equipment for Electrolysis Training Programs.

(1) An electrolysis training program shall: have the following equipment in good working condition, in sufficient numbers, and supplies in sufficient amount to enable students to meet their learning objectives:

(b) Have a working U.S. FDA registered blend epilator, and,

(c) U.S. FDA registered galvanic epilator with multiple needle apparatus,

(c) Comply with the requirements of Rule 64B8-51.006(3), F.A.C.

(d) Magnifying device or treatment lamp,

(e) Treatment table or treatment chair,

- (f) Operator stool or chair,
- (g) Autoclave with chemical biological indicators,
- (h) Dry heat sterilizer with chemical biological indicators,
- (i) Needles (e.g. probes) of various sizes,
- (j) Forceps (e.g. tweezers),
- (k) Needle holder tips,

(I) Ultrasonic cleaner with enzyme dissolving detergent,

- (m) Covered holding containers for contaminated instruments,
- (n) Sharps containers for disposal of used needles and other sharp instruments in accordance with the biomedical waste disposal requirements of Rule Chapter 64E-16, F.A.C.,
 - (o) Non-sterile disposable examination gloves,
 - (p) Waste receptacles,
 - (q) Soaps,
 - (r) Paper towels,
 - (s) Paper table coverings,

(t) Tuberculocidal hospital grade disinfectant detergent,

(u) Betadine, 3% U.S. Pharmaceutical grade hydrogen peroxide and 70% isopropyl alcohol or wrapped, single use wipes

⁽a) Have a working U.S. FDA registered short wave epilator,

saturated with 70% isopropyl alcohol,

(v) Clean non-sterile materials such as cotton balls, cotton strips, cotton swabs, gauze pads, and gauze strips,

(w) Clean, covered containers for creams, lotions and ointments with single use spatulas or containers which are pump or tube type dispensers,

(x) Magnifying device which shall be a magnifying lamp, optical loupe or microscope.

(y) Reference books/textbooks in the following areas:

1. Electrolysis;

2. Dermatology;

3. Anatomy; and

4. Medical dictionary.

(2) Endodontic dry heat sterilizers, also known as glass bead sterilizers, shall not be used in place of an autoclave or dry heat sterilizer in paragraphs 64B8-53.003(1)(g) and (h), F.A.C.

<u>Rulemaking</u>Specific Authority 478.43(4), 478.50(4)(b) FS. Law Implemented 456.033, 478.43(4), 478.45(1)(e), 478.50(4)(b) FS. History–New 11-16-93, Formerly 61F6-78.003, 59R-53.003, Amended 11-13-97, 10-12-98.

• 64B8-50.003 Delegation of Powers & Duties to Electrolysis Council

On April 20, 2016, the First District Court of Appeals affirmed the Division of Administrative Hearing's recommendation that Petitions for Declaratory Statement should be heard by the Board of Medicine without need for initial review by the Council. Ms. Norr presented the following corresponding changes for the Council's approval.

64B8-50.003 Delegation of Powers and Duties to Electrolysis Council.

(1) Pursuant to Section 478.43, F.S., the Board delegates to the Electrolysis Council the following powers and duties.

- (a) Approval and denial of applicants for examination and applicants for endorsement.
- (b) Approval and denial of continuing education providers and electrolysis training programs.
- (c) The authority to accept non-disciplinary voluntary relinquishments.
- (d) The authority to notice rules for development and to propose rules to the Board.

(2) Rulemaking proposals, petitions for declaratory statement and petitions to adopt, amend, or repeal rules, relating which relate to the practice of electrology shall first be presented to the Council. The Council shall consider the matter and make recommendations to the Board as to the appropriate action to be taken.

Rulemaking Authority 478.43(1) FS. Law Implemented 478.43(3) FS. History–New 5-31-93, Formerly 21M-75.003, Amended 11-16-93, Formerly 61F6-75.003, 59R-50.003, Amended 2-11-08, 2-15-10.

Following discussion, Ms. Greenhalgh moved to approve the proposed language as presented. Ms. Lapeyrouse seconded the motion, which carried 5/0.

Ms. Greenhalgh moved that the proposed language would not have an adverse impact on small business nor have an economic impact on government or any other entity in excess of \$200,000 within one year of the rule being implemented. Ms. Lapeyrouse seconded the motion, which carried 5/0.

Review of Proposed Revisions to Facility Application Forms: Rule 64B8-51.006 (2)(b) and (5)(b)1., F.A.C., Rule Governing Licensure and Inspection of Electrology Facilities

Council staff presented proposed changes to the Electrolysis Facility "New or Change of Ownership Facility Application" and "Transfer of Location Application" Forms to include the following:

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- separation of applications into two separate forms to eliminate confusion for applicants frequently unsure of which form to complete;
- streamlining of instructions and related information for both applications;
- addition of required notification regarding e-mail addresses being public records;
- new section to allow applicants to specify the practice modality type;
- expanded Ownership Information section to allow for particular specification of business entity type;
- expanded Licensed Electrologist listing section to allow for provision of information on the satisfaction of requirements in Rule 64B8-51.006(3)(g), F.A.C., regarding laser hair removal services; and
- new sections to allow applicants to disclose any history issues relevant to issuance of the license.

Following discussion, Ms. Greenhalgh moved to approve the proposed changes to Rules 64B8-51.006 (2)(b) and (5)(b)1., F.A.C., as well as the incorporated forms, to include adding an option for CME <u>or Equivalent</u> where that information is requested on each form. Ms. Lapeyrouse seconded the motion, which carried 5/0.

Ms. Greenhalgh moved that the proposed language would not have an adverse impact on small business nor have an economic impact on government or any other entity in excess of \$200,000 within one year of the rule being implemented. Ms. Lapeyrouse seconded the motion, which carried 5/0.

REPORT OF ASSISTANT ATTORNEY GENERAL – Lynette Norr

6. Rule Status Report

Ms. Norr presented the status of rules in progress, to include an update on Rule 64B8-51.001, F.A.C., Manner of Application, approved by the Council on November 9, 2015 and the Board of Medicine on April 8, 2016. The rule was noticed for development on May 9, 2016.

- 64B8-51.001 Manner of Application
- 64B8-51.006 Rule Governing Licensure and Inspection of Electrology Facilities
- 64B8-51.007 Fees for Examination, Examination Review and Initial Licensure
- 64B8-52.004 Requirements for Approval of Training Courses for Laser and Light-Based Hair Removal or Reduction
- 64B8-53.001 Requirements for Electrolysis Training Programs Approved by the Board
- 64B8-53.002 Curriculum Standards for Electrolysis Training Programs
- 64B8-53.003 Required Equipment for electrolysis Training Programs
- 64B8-54.0041 Special Assessment Fee
- 64B8-55.001 Disciplinary Guidelines
- 64B8-55.002 Citations
- 64B8-56.002 Equipment and Devices; Protocols for Laser and Light-Based Devices

7. Sunshine Laws Refresher, Lynette Norr

This item was tabled to July 11th meeting.

REPORTS

8. Council Chair – Jolynn Greenhalgh, DNP, ARNP Healthiest Weight Update

Ms. Greenhalgh indicated plans to attend the next Board of Medicine meeting regarding her application for re-appointment to the Council. Ms. Greenhalgh's term is due to expire on July 9, 2016.

9. Executive Director – Allen Hall

- Cash Balance Report
- Expenditures by Function

Informational Item.

NEW BUSINESS

10. 2016 Legislative Update

Informational Item.

11. CS/CS/HB941 – Department of Health

• Rule 64B8-51.001, F.A.C., Manner of Application

The Board reviewed changes to the Electrologist licensure application form incorporating updates pursuant to the passage of CS/CS/HB 941 (2016). The form reflects removal of the requirement to complete a two-hour prevention of medical errors course for initial licensure and removed the exemption that would allow applicants who committed certain acts defined in Section 456.0635, F.S., to continue with licensure if he or she completed a related training program prior to July 9, 2009.

Ms. Greenhalgh moved to approve the form and associated rule. Ms. Grillo seconded the motion, which carried 5/0.

Ms. Greenhalgh moved that the proposed language would not have an adverse impact on small business nor have an economic impact on government or any other entity in excess of \$200,000 within one year of the rule being implemented. Ms. Grillo seconded the motion, which carried 5/0.

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12. 2017 Proposed Council Meeting Dates

The following meeting dates were presented for the 2017 Electrolysis Council General Business meeting.

- January 9
- April 24
- July 24
- October 23

OLD BUSINESS

13. January 25, 2016 Electrolysis Council Meeting Minutes

Ms. Greenhalgh moved to approve the January 25, 2016 Electrolysis Council meeting minutes. Ms. Lapeyrouse seconded the motion, which carried 5/0.

OTHER BUSINESS AND INFORMATION

14. Electronic Agenda Implementation

The Division of Medical Quality Assurance is transitioning regulatory boards and councils from paper-based agenda material books to electronic agendas. The Electrolysis Council is scheduled to make this transition during its next meeting scheduled for July 11, 2016.

15. Staff Recognition

Informational Item

ADDITIONAL INFORMATIOM

16. April 7, 2016 Board of Medicine Rules/Legislative Committee Minutes

Informational Item.

17. Granting of Petition for Variance/Waiver: Jennifer Fraunfelter re: Rule 64B8-53.002, F.A.C.

Informational Item.

ADJOURNMENT

The meeting adjourned at 5:01 p.m.

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