

BROCATO & SHATTUCK

Date:	Friday, March 8, 2024
Committee:	Senate Finance Committee
	The Honorable Pam Beidle, Chair
Bill:	Senate Bill 995 – Health - Laser Hair Removal - Requirements (Laser Hair Removal Act)
Position:	OPPOSE

On behalf of our client the Maryland Dermatologic Society we submit the following testimony in opposition to Senate Bill 995.

As drafted the bill creates a new subtitle under the Health General Article specific to laser hair removal. Currently laser hair removal procedures fall under the purview of regulations in "Title 10 MARYLAND DEPARTMENT OF HEALTH, Subtitle 32 BOARD OF PHYSICIANS, Chapter 09 Delegation and Assignment of Performance of Cosmetic Medical Procedures and Use of Cosmetic Medical Devices" (see Attachment 1). These regulations were developed over a period of years after much debate and deliberation by the physicians and health care providers involved. They represent a solid foundation which provides clarity to those engaged in cosmetic procedures, and education and training safeguards to ensure the protection and safety of patients.

The bill proposes a number of changes that move away from these essential protections. The proposed changes would:

- include additional providers as laser hair removal practitioners not currently covered or contemplated by Maryland regulation,
- minimize the physician's physical presence and oversight at the laser hair facility, and
- reduce educational and training requirements.

These specific areas of concern are highlighted in Attachment 2 which highlights proposed changes to the bill that address these concerns.

We appreciate the willingness of the proponents to meet with the Maryland Dermatologic Society and are glad to continue discussions to maintain the important patient safety standards in current regulations.

Until these concerns are resolved we ask for an UNFAVORABLE report on Senate Bill 995.

For more information: Dan Shattuck – <u>dans@bmbassoc.com</u> Russ Kujan, Executive Director, Maryland Dermatologic Society –<u>rkujan@medchi.org</u>

Title 10 MARYLAND DEPARTMENT OF HEALTH

Subtitle 32 BOARD OF PHYSICIANS

Chapter 09 Delegation and Assignment of Performance of Cosmetic Medical Procedures and Use of Cosmetic Medical Devices

Authority: Health Occupations Article, §§14-205, 14-306, 14-404, 14-606, and 15-302, Annotated Code of Maryland

.01 Scope.

A. This chapter governs the performance, delegation, assignment, and supervision of cosmetic medical procedures, and the use of cosmetic medical devices by a physician or under a physician's direction.

B. This chapter does not govern use of medical procedures or medical devices for the purpose of treating a disease.

C. This chapter does not endorse or certify the safety of any cosmetic medical device or cosmetic medical procedure.

D. This chapter does not authorize the delegation of any duties to any person who is not licensed under Health Occupations Article, Annotated Code of Maryland.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

- B. Terms Defined.
 - (1) "ACCME" means the Accreditation Council on Continuing Medical Education.
 - (2) "ACGME" means the Accreditation Council for Graduate Medical Education.

(3) "AOA" means the American Osteopathic Association.

(4) Cosmetic Medical Device.

(a) "Cosmetic medical device" means a device that alters or damages living tissue.

(b) "Cosmetic medical device" includes any of the following items, when the item is used for cosmetic purposes:

(i) Laser;

(ii) Device emitting light or intense pulsed light;

(iii) Device emitting radio frequency, electric pulses, or sound waves; and

(iv) Devices used for the injection or insertion of foreign or natural substances into the skin, fat, facial tissue, muscle, or bone.

(5) Cosmetic Medical Procedure.

(a) "Cosmetic medical procedure" means a procedure using a cosmetic medical device or medical product to improve an individual's appearance.

(b) "Cosmetic medical procedure" includes the following:

(i) Skin treatments using lasers;

(ii) Skin treatments using intense pulsed light;

(iii) Skin treatments using radio frequencies, microwave, or electric pulses;

(iv) Chemical peels that ablate living skin tissue;

(v) Skin treatments with phototherapy;

(vi) Dermabrasion;

(vii) Subcutaneous, intradermal, or intramuscular injections of medical products;

(viii) Treatments intended to remove or cause destruction of fat; and

(ix) Any treatment using a cosmetic medical device for the purpose of improving an individual's appearance.

(6) "Delegate" means to entrust a duty to a physician assistant under Health Occupations Article, Title 15, Annotated Code of Maryland.

(7) "Delegation" means the entrusting of a duty by a physician to a physician assistant under Health Occupations Article, Title 15, Annotated Code of Maryland.

(8)"Dermabrasion" means an abrasive process to remove epidermis and superficial dermis, resulting in a smoothing of contour irregularities.

(9) "Direct supervision" means oversight exercised by a supervising physician who is:

(a) In the physical presence of a non-physician and a patient; and

(b) Instructing the non-physician in the performance of a cosmetic medical procedure, or observing the performance of a non-physician being trained in the procedure.

(10) "Immediately available supervision" means the responsibility of a licensed physician to provide necessary direction in person, by telephone, or by other electronic means.

(11) "Non-Physician" means an individual who:

- (a) Meets the requirements of Regulation .04 of this chapter; and
- (b) Is not licensed in Maryland as a physician.
- (12) "On-site supervision" means oversight exercised by a supervising physician who is:
 - (a) Present at the site; and
 - (b) Able to respond in person during a delegated or assigned cosmetic medical procedure.
- (13) "Physician assistant" means a physician assistant with a current certificate to practice in Maryland.

.03 Physician Qualifications.

A. License. A physician shall obtain a license to practice medicine in Maryland before the physician may perform, delegate, assign, or supervise cosmetic medical procedures or the use of cosmetic medical devices.

B. Education.

(1) A physician who performs, assigns, supervises, or delegates the performance of cosmetic medical procedures by a non-physician first shall obtain training in the indications for and performance of the cosmetic medical procedures and operation of any cosmetic medical device to be used.

(2) Training programs provided by a manufacturer or vendor of cosmetic medical devices or supplies may not be a physician's only education in the cosmetic medical procedures or the operation of the cosmetic medical devices to be used.

(3) ACCME or AOA approved continuing education, or completion of an ACGME or AOA accredited postgraduate program that includes training in the cosmetic medical procedure performed satisfies this requirement.

.04 Qualifications of Individual to Whom Acts May Be Delegated and Assigned.

A. A cosmetic medical procedure may be delegated to a physician assistant or assigned to any other health care provider licensed under Health Occupations Article, Annotated Code of Maryland, whose licensing board has determined that the procedure falls within the provider's scope of practice.

B. A physician may not permit any individual who performs cosmetic medical procedures delegated or assigned by that physician to operate a cosmetic medical device or perform a cosmetic medical procedure unless the individual has received:

(1) Training as described in Regulation .07 of this chapter; and

(2) Any training required by that individual's health occupations board.

.05 Physician Responsibilities.

A. A physician shall:

(1) Develop and maintain at each site where the delegated, assigned, or supervised cosmetic medical procedures will be rendered written office protocols for each such cosmetic medical procedure;

(2) Personally perform the initial assessment of each patient;

(3) Prepare a written treatment plan for each patient, including diagnosis and planned course of treatment and specification of the device and device settings to be used;

(4) Obtain informed consent of the patient to be treated by a non-physician;

(5) Except as indicated in §B or C of this regulation, provide onsite supervision whenever a non-physician is performing cosmetic medical procedures or using cosmetic medical devices;

(6) Retain responsibility for any acts delegated to a non-physician; and

(7) Create and maintain medical records in a manner consistent with accepted medical practice and in compliance with Health-General Article, Title 4, Subtitles 3 and 4, Annotated Code of Maryland, and with Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. §1320d-2, as amended, and 45 CFR Parts 160 and 164, as amended).

B. The Board may approve a delegation agreement for a physician assistant that permits the physician to delegate performance of cosmetic medical procedures under immediately available supervision after the physician has evaluated the patient and developed a written treatment plan.

C. A delegation agreement for a physician assistant that includes cosmetic medical procedures and is approved by the Board before May 2009, is not affected by this chapter.

.06 Written Protocols.

Written protocols for cosmetic medical procedures and equipment shall include the following:

A. List of all equipment, including:

- (1) Manufacturer's specifications;
- (2) Operating instructions; and
- (3) Maintenance log;
- B. Documentation regarding initial and periodic training of all users of the equipment;
- C. Role of the physician for each procedure;
- D. Role of the non-physician for each procedure;
- E. Steps to address common complications and emergency situations; and
- F. Appropriate care and follow-up for the patient after the procedure.

.07 Training of Non-Physicians.

A. The physician is responsible for assuring that any individual to whom the physician delegates or assigns the performance of a cosmetic medical procedure or the operation of a cosmetic medical device is properly trained. Training shall include both theoretical instruction and clinical instruction.

- B. Theoretical instruction shall include:
 - (1) Cosmetic-dermatological indications and contraindications for treatment;
 - (2) Identification of realistic and expected outcomes of each procedure;
 - (3) Selection, maintenance, and utilization of equipment;
 - (4) Appropriate technique for each procedure, including infection control and safety precautions;
 - (5) Pharmacological intervention specific to the procedure;
 - (6) Identification of complications and adverse reactions for each procedure;
 - (7) Emergency procedures to be used in the event of:
 - (a) Complications;
 - (b) Adverse reactions;
 - (c) Equipment malfunction; or
 - (d) Any other interruption of a procedure; and
 - (8) Appropriate documentation of the procedure in the patient's chart.
- C. Clinical instruction shall include:

(1) Observation of performance of the procedure or use of the device by an individual experienced in performing the procedure; and

(2) Performing the procedure or using the device under the direct supervision of the delegating physician who is present and observing the procedure a sufficient number of times to assure that the non-physician is competent to perform the procedure without direct supervision.

.08 Non-Physician's Responsibility.

A. A physician who delegates or assigns a cosmetic medical procedure or the use of a cosmetic medical device to a non-physician or who supervises a non-physician performing these functions shall assure that the non-physician complies with this regulation.

B. A non-physician may not use a cosmetic medical device or perform a cosmetic medical procedure unless the individual has received:

(1) The training described in Regulation .07 of this chapter; and

(2) Any training required by that individual's health occupations board.

C. A non-physician shall:

(1) Review and follow the written protocol with respect to a cosmetic medical procedure;

(2) Verify that the physician has assessed the patient and given written treatment instructions for the procedure;

(3) Discuss the procedure with the patient to ensure that the patient:

(a) Is aware that the treatment will be provided by a non-physician; and

(b) Has given consent in writing to treatment by a non-physician;

(4) Notify the delegating physician about any adverse events or complications before the patient leaves the site;

(5) Document all relevant details of the procedure in the patient's chart, including any adverse events and complications; and

(6) Satisfy any requirements imposed by the licensing board of the non-physician.

.09 Grounds for Discipline.

A. Physician. A physician may be disciplined for any of the following:

(1) Delegating, assigning, or supervising a cosmetic medical procedure performed by an individual who is not a physician assistant or another licensed health care provider whose licensing board has determined that the procedure is within the scope of practice of the individual;

(2) Delegating cosmetic medical procedures to an individual who has not had:

(a) The training specified in Regulation .07 of this chapter; and

- (b) The training required by that individual's health occupations board; or
- (3) Failure to adhere to any requirement of this chapter.

B. Non-Physician. A non-physician who violates any provision of this chapter is guilty of the practice of medicine without a license and may be subject to a fine of not more than \$50,000 under Health Occupations Article, \$14-606, Annotated Code of Maryland.

C. Other Individual. An individual using a cosmetic medical device or performing a cosmetic medical procedure who is not a licensed physician and is not authorized to perform the cosmetic medical procedure under this chapter, or under regulations promulgated by another licensing board established by Health Occupations Article, Annotated Code of Maryland, is guilty of the practice of medicine without a license and may be subject to a fine of not more than \$50,000 under Health Occupations Article, \$14-606, Annotated Code of Maryland.

Administrative History

Effective date: August 23, 2010 (37:17 Md. R. 1185)

Regulation .02B amended effective March 14, 2016 (43:5 Md. R. 386); December 31, 2018 (45:26 Md. R. 1246)

Attachment # 2

SENATE BILL 995

J3, J2, J1

4lr2449

By: **Senator Klausmeier** Introduced and read first time: February 2, 2024 Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

$\frac{2}{3}$

Health – Laser Hair Removal – Requirements (Laser Hair Removal Act)

FOR the purpose of prohibiting an individual from performing or attempting to perform a
laser hair removal procedure unless the individual is a certain health professional;
establishing certain requirements for the performance of laser hair removal
procedures and laser hair removal practitioners; requiring certain physician
oversight of laser hair removal facilities and laser hair removal procedures
performed by laser hair removal practitioners; and generally relating to laser hair
removal procedures.

11 BY adding to

- 12 Article Health General
- Section 19–3D–01 through 19–3D–04 to be under the new subtitle "Subtitle 3D.
 Laser Hair Removal"
- 15 Annotated Code of Maryland
- 16 (2023 Replacement Volume)
- 17 Preamble

18 WHEREAS, Laser hair removal is a medical procedure, and its practice by 19 unqualified persons presents a danger to the public health and safety; and

WHEREAS, Because it is difficult for the public to make informed choices relating to laser hair removal services and the consequences of wrong choices can harm the public health and safety, laser hair removal must be performed only by persons who possess the proper licensure and skills; and

WHEREAS, Restrictions should be imposed, however, only to the extent necessary to protect the public and in a manner that will not unreasonably affect the competitive market for the safe and effective delivery of such services; now, therefore,

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW. [Brackets] indicate matter deleted from existing law.

sb0995

SENATE BILL 995

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, 1 $\mathbf{2}$ That the Laws of Maryland read as follows: 3 Article – Health – General 4 SUBTITLE 3D. LASER HAIR REMOVAL. 519-3D-01. 6 **(**A**)** IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS 7 INDICATED. "HEALTH PROFESSIONAL" MEANS AN INDIVIDUAL: 8 **(B)** 9 (1) WHO IS LICENSED OR CERTIFIED AS A PHYSICIAN, A PHYSICIAN 10 ASSISTANT, AN ADVANCED PRACTICE REGISTERED NURSE, A REGISTERED NURSE, OR A **LICENSED PRACTICAL NURSE** UNDER THE HEALTH OCCUPATIONS ARTICLE; 11 12 AND FOR WHOM THE PERFORMANCE OF A LASER HAIR REMOVAL 13 (2) 14 PROCEDURE IS WITHIN THE SCOPE OF THE INDIVIDUAL'S LICENSE OR 15**CERTIFICATION. (C)** "LASER HAIR REMOVAL FACILITY" MEANS A BUSINESS LOCATION THAT 16 17PROVIDES LASER HAIR REMOVAL AND IS ZONED FOR MEDICAL USE. 18 **(**D**)** "LASER HAIR REMOVAL **PRACTITIONER''** MEANS Α HEALTH 19 PROFESSIONAL WHO PRACTICES LASER HAIR REMOVAL. "LASER HAIR REMOVAL PROCEDURE" MEANS THE USE OF A LASER 20**(E)** (1) $\underline{21}$ LIGHT-BASED DEVICE TO PERFORM A NONABLATIVE HAIR REMOVAL PROCEDURE 22THAT DOES NOT REMOVE THE EPIDERMIS. PERMANENT HAIR REMOVAL. "LASER HAIR REMOVAL PROCEDURE" DOES NOT INCLUDE 23(2) 24ELECTROLOGY. 19-3D-02. 2526THIS SUBTITLE MAY NOT BE CONSTRUED TO RESTRICT OR LIMIT AN 27INDIVIDUAL LICENSED OR CERTIFIED UNDER THE HEALTH OCCUPATIONS ARTICLE 28FROM ENGAGING IN A PRACTICE FOR WHICH THE INDIVIDUAL IS DULY LICENSED OR

29 CERTIFIED UNDER THAT ARTICLE.

 $\mathbf{2}$

1 **19–3D–03.**

2 (A) AN INDIVIDUAL MAY NOT PERFORM OR ATTEMPT TO PERFORM A LASER 3 HAIR REMOVAL PROCEDURE UNLESS THE INDIVIDUAL IS A HEALTH PROFESSIONAL.

4 (B) A LASER HAIR REMOVAL PRACTITIONER MAY PERFORM A LASER HAIR 5 REMOVAL PROCEDURE ONLY USING LASERS APPROVED BY THE U.S. FOOD AND 6 DRUG ADMINISTRATION FOR NONINVASIVE PROCEDURES.

7 (C) (1) A LASER HAIR REMOVAL PRACTITIONER WHO IS NOT A PHYSICIAN 8 SHALL COMPLETE A LASER HAIR REMOVAL PRACTITIONER TRAINING AND 9 EDUCATION PROGRAM.

10 (2) THE TRAINING AND EDUCATION PROGRAM REQUIRED UNDER 11 PARAGRAPH (1) OF THIS SUBSECTION:

12 (I) MAY BE COMPLETED:

131.AT A LASER HAIR REMOVAL FACILITY AT WHICH THE14LASER HAIR REMOVAL PRACTITIONER PROVIDES LASER HAIR REMOVAL15PROCEDURES; OR

162.USING A PROGRAM PROVIDED BY A THIRD PARTY IF17THE PROGRAM IS UNDER THE OVERSIGHT OF A PHYSICIAN; AND

18 (II) SHALL INCLUDE AT LEAST 40 HOURS OF TRAINING, WHICH 19 MAY CONSIST OF ANY COMBINATION OF DIDACTIC TRAINING, IN-PERSON HANDS-ON 20 TRAINING, AND THE PERFORMANCE OF LASER HAIR REMOVAL PROCEDURES.

(C) (1) A LASER HAIR REMOVAL PRACTITIONER WHO IS NOT A PHYSICIAN WHOSE RESIDENCY TRAINING/RECERTIFICATION INCLUDES THE USE OF LASERS FOR LASER HAIR REMOVAL SHALL COMPLETE A LASER HAIR REMOVAL TRAINING AND EDUCATION PROGRAM.

(2) THE TRAINING AND EDUCATION PROGRAM REQUIRED UNDER PARAGRAPH (1) OF THIS SUBSECTION:

(I) MAY NOT BE COMPLETED AT A LASER HAIR REMOVAL FACILITY, AND SHALL BE COMPLETED AT A THIRD PARTY ACCREDITED CONTINUING EDUCATION COURSE. (II) THAT COURSE SHALL INCLUDE AT LEAST 40 HOURS CME TRAINING.

- 1. <u>THIS TRAINING MUST BE ACCREDITED CONTINUING EDUCATION TRAINING</u> <u>AND NOT PROVIDED BY A LASER MANUFACTURER OR AN EMPLOYEE OF A</u> <u>LASER MANUFACTURER, OR BY A PHYSICIAN DIRECTLY BEING PAID BY A</u> <u>LASER MANUFACTURER.</u>
- 2. <u>THE CME TRAINING MAY CONSIST OF ANY COMBINATION OF DIDACTIC OR</u> <u>HANDS ON TRAINING.</u>

21 **19–3D–04.**

22 (A) A LASER HAIR REMOVAL FACILITY SHALL BE OVERSEEN BY A 23 PHYSICIAN, ONSITE AND IMMEDIATELY AVAILABLE.

24 **(B)** A PHYSICIAN THAT PROVIDES OVERSIGHT FOR A LASER HAIR REMOVAL 25 FACILITY SHALL:

(1) ESTABLISH PROPER PROTOCOLS FOR LASER HAIR REMOVAL
PROCEDURES PROVIDED AT THE LASER HAIR REMOVAL FACILITY, INCLUDING
PROTOCOLS FOR THE MANAGEMENT OF PROCEDURE COMPLICATIONS INVOLVING
THE USE OF A PHYSICIAN, A PHYSICIAN ASSISTANT, OR AN ADVANCED PRACTICE
REGISTERED NURSE;

1 (2) DETERMINE THE NUMBER OF LASER HAIR REMOVAL 2 PRACTITIONERS UNDER THE PHYSICIAN'S SUPERVISION AT THE LASER HAIR 3 REMOVAL FACILITY; AND

4 (3) REVIEW AT LEAST 10% 50% OF ALL LASER HAIR REMOVAL 5 RECORDS. PATIENT

6 (C) A PHYSICIAN IS NOT REQUIRED TO BE PHYSICALLY PRESENT OR 7 IMMEDIATELY AVAILABLE TO SUPERVISE LASER HAIR REMOVAL PROCEDURES, BUT 8 MAY BE AVAILABLE FOR COMMUNICATION DURING THE PROCEDURE IN PERSON OR 9 BY TWO-WAY, REAL-TIME, INTERACTIVE COMMUNICATION.

10 (D) A LASER HAIR REMOVAL PRACTITIONER:

11(1) SHALL FOLLOW WRITTEN PROTOCOLS ESTABLISHED AND12REVISED, AS NECESSARY, BY A PHYSICIAN UNDER SUBSECTION (B) OF THIS SECTION;13AND

14(2) MAY PERFORM LASER HAIR REMOVAL PROCEDURES ON A15PATIENT WITHOUT:

16 (I) A PRIOR DIAGNOSIS OR INITIAL ASSESSMENT OF THE 17 PATIENT HAVING BEEN MADE BY A PHYSICIAN; OR AND

18(II) AN INDIVIDUAL TREATMENT PLAN HAVING BEEN19PREPARED BY A PHYSICIAN.

20 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 21 October 1, 2024.

4