

# 10.32.~~109~~11 Delegation and Assignment of Performance of Cosmetic Medical Procedures and Use of Cosmetic Medical Devices

## .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) (7) "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.] *the supervisor is physically present on the premises, personally treating the patient, and in the presence of the patient while services are provided*~~

~~(10) (8) "Immediately available supervision" means [the responsibility of a licensed physician to provide necessary direction in person, by telephone, or by other electronic means.] *to provide necessary direction in person, by telephone, or by other electronic means.*~~

~~(11) (9) "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.] *the responsibility of the supervisor to provide necessary direction and is:*~~

~~(a) *Physically present in the facility; and*~~

~~(b) *Able to respond immediately in person.*~~

~~(13) (10) "Physician assistant" means [a physician assistant with a current certificate to practice in Maryland.] *an individual who is licensed by the Board to practice as a physician assistant.*~~

### **.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 on-site 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.]~~  
*A collaboration agreement may permit one or more patient care team physicians to delegate the performance of cosmetic 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:]~~ *Prohibited Conduct.***

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 Individuals. 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.

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