

2021 DEADLINE DATES FOR DELEGATION AGREEMENTS WITH ADVANCED DUTIES

These deadline dates pertain to PAs submitting delegation agreement addendums for advanced duties who are either:

- Employed by an accredited hospital or surgi-center, but the hospital's or surgi-center's governing body has not approved a delineation of privileges allowing the PA to perform the requested duty (duties): OR
- Private practice, detention center, public health facility, correctional facility.

The Physician Assistant Advisory Committee (PAAC) must review the delegation agreement addendums for advanced duties prior to going to the Board for approval. Deadline dates for Board materials may be due before the PAAC meets. Therefore, addendums will be presented at the next available Board meeting for approval after the PAAC has reviewed them.

<u>Deadline Dates</u>	<u>PAAC Meeting Dates</u>	<u>Board Meeting Dates</u>
December 14, 2020	January 6, 2021	January 27, 2021
January 11, 2021	February 3, 2021	February 24, 2021
February 8, 2021	March 3, 2021	March 24, 2021
March 15, 2021	April 7, 2021	April 28, 2021
April 12, 2020	May 5, 2021	May 26, 2021
May 10, 2021	June 2, 2021	June 23, 2021
June 14, 2021	July 7, 2021	July 28, 2021
July 12, 2021	August 4, 2021	August 25, 2021
August 9, 2021	September 1, 2021	September 15, 2021
September 13, 2021	October 6, 2021	October 20, 2021
October 11, 2021	November 3, 2021	November 17, 2021*
November 8, 2021	December 1, 2021	December 15, 2021*

The Maryland Board of Physicians **must** receive the advanced duties addendum by the published deadline date to be considered for Board approval. **The Board will not accept faxed copies of delegation agreements addendums.**

Reminders:

1. **Delegation Agreement Addendum:** Complete and sign all sections of the delegation agreement addendum (DAA) for advanced duties. DAAs may be returned to the PA for the following reasons:
 - a. Incomplete sections;
 - b. Missing signatures;
 - c. A copy of signatures instead of the original signature.

2. **Copies:** BOTH Physician Assistants and Primary Supervising Physicians should keep a

copy of the delegation agreement for their records **PRIOR** to mailing. **If you request a copy of the delegation after it was mailed, it may take up to 30 days to receive the copy.**

3. **Delegation Agreement Addendum for Advanced Duties:** Supporting documentation, i.e., delineation of privileges, description of education, training and experience, certificates, procedure logs, etc., must accompany the DAA. *The processing of the DAA will be delayed if the appropriate supporting documentation is not included. The delineation of privileges must be accompanied by an approval letter from the governing body, e.g. Board of Trustees, CEO/President.*
4. **Approval Letter:** The approval letter will be emailed to the supervising physician and the physician assistant. Please be sure to provide a valid email address.
5. **Prescriptive Authority:** If the primary supervising physician delegates the prescribing of **controlled dangerous substances** to a physician assistant. The physician assistant must:
 - a. Obtain a Maryland Controlled Dangerous Substance (MCDS) license from the Office Controlled Substances Administration. Include a copy of your approval email with the request for MCDS; and
 - b. After obtaining an MCDS license, register with the Drug Enforcement Administration (DEA).
6. **Reporting Changes in Employment Status:** Hospitals, related institutions, alternative health care systems, or employers are required to report to the Board any termination of employment of the physician assistant for any reason, including quality of care issues within 5 days of the termination.

Hospitals, related institutions, alternative health care systems, or employers are also required to report to the Board within 5 days any limitation, reductions or other changes of employment of the change of employment that might be grounds for disciplinary actions under Health Occupations Article, §15-314.

****Please note: Asterisks (*) indicates meeting scheduled accordingly due to holidays.**

MARYLAND BOARD OF PHYSICIANS

P.O. Box 2571

Baltimore, MD 21215

www.mpb.state.md.us

DELEGATION AGREEMENT ADDENDUM FOR ADVANCED DUTIES

Note: This application is an addendum to your approved delegation agreement. You may use this form if you have an approved delegation agreement on file with the Board. You may also submit this addendum with a new delegation agreement, if applicable. Be sure to include the appropriate documentation.

All delegation agreement addendums for advanced duties must be filed with the Board.

Dear Primary Supervising Physician and Physician Assistant:

The attached application reflects the changes to the law that went into effect on October 1, 2010. The new law changes the processing of requests to perform advanced duties in some practice settings.

The Board is no longer required to provide prior approval of a delegation agreement containing advanced duties for physician assistants who are employed by accredited hospitals and accredited ambulatory surgical facilities if the facility meets certain criteria.

A PA credentialed by an accredited facility may begin working after the Board receives the completed delegation agreement with the advanced duties and acknowledges receipt of the delegation agreement containing advanced duties.

For non-accredited hospitals, non-accredited ambulatory surgical facilities and other types non-accredited practice settings, PAs must obtain prior Board approval before they begin practicing any advanced duty. PAs in these practice settings are required to submit training and education documentation.

The Allied Health Division
Physician Assistant Program
Maryland Board of Physicians

MARYLAND BOARD OF PHYSICIANS

P.O. Box 2571

Baltimore, MD 21215

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DELEGATION AGREEMENT ADDENDUM FOR ADVANCED DUTIES

FOR ALL PRACTICE SETTINGS

This application is an addendum to your approved delegation agreement. You may use this form if you have an approved delegation agreement on file with the Board. You may also submit this addendum with a new delegation agreement, if applicable. Be sure to include the appropriate documentation.

Instructions and Important Information

1. **Practice Setting:** Choose the appropriate setting where procedure(s) will be performed. If the setting is accredited, provide the name of the accrediting agency. Accredited settings are specific to hospitals and ambulatory surgical centers.
2. **Physician Assistant Information:** Complete all requested information.
3. **Primary Supervising Physician Information:** Complete all requested information.
4. **Practice Location:** Complete this section. For more than one practice setting, use a separate sheet of paper.
5. **Practice Contact Information:** Complete all requested information. The Board will email notification, approval or temporary practice letters to the PA and the primary supervising physician. This may be the only communication you receive. Please provide a valid email address. It is the responsibility of the PA to provide copies of the letter to the medical staff office, office manager, etc. of the practice.
6. **Scope of Practice:** Choose appropriate scope of practice.
7. **Delegated Advanced Duties*:** List the procedure(s) that are being delegated to the PA. Examples: Cosmetic procedures, lumbar punctures, central/arterial line insertions, endoscopic procedures, stress testing, etc.
8. **Approval by an Accredited Healthcare Facility. For this question, please check the appropriate box (A, B, or C).**
 - A. PAs employed by an accredited health care facility** or ambulatory surgical center** and who have been credentialed to perform the requested procedure(s) must submit an approved delineation of privileges containing the requested advanced procedures. *The delineation must be approved by the hospital or ambulatory surgical centers governing body, e.g. Board of Trustees, president, CEO.*
 - B. As employed by accredited hospitals or ambulatory surgical centers who have not been credentialed to perform the requested procedures must submit a procedure log for each requested procedure.
 - C. PAs employed in any other practice setting must submit a procedure log for each requested procedure.

*Advanced duties” means medical acts that require additional training beyond the basic physician assistant education program required for licensure.

**Accredited by The Joint Commission, the American Association for Accreditation of Ambulatory Surgical Facilities, the Accreditation Association for Ambulatory Health Care or certification to participate in the Medicare program, as enacted by Title XVIII of the Social Security Act.

Instructions and Important Information Continued

- Procedures logs should include at least 10-25 of each successfully completed procedure, the date of the procedure, type of procedure, the name of the PA and the signature of the supervising physician attesting that the PA completed the requested procedures.
 - Procedures logs should not include the name, date of birth, or social security numbers of the patient.
9. **Qualifications of Physician Assistant:** Provide a detailed description of the additional training and education that prepared the PA to perform requested procedures. Please attach copies of training certificates or other documentation of training.
10. **Qualifications of Primary or Alternate Supervising Physician:** Complete this section if the delegated medical acts are outside the normal scope of practice of primary or alternate supervising physician. Physicians who are delegating cosmetic procedures must meet the criteria in COMAR 10.32.09 Delegation of Cosmetic Regulations before they may supervise a PA. **See Appendix C**
11. **Supervision:** Choose one or more methods of supervision.
12. **Attestations:** The primary supervising physician must complete this section.

APPENDIXES

Appendix A—Temporary Practice Letter: For delegation agreements with advanced duties that require prior Board approval, the PA and primary supervising physician may apply for a temporary practice letter. The Board may approve a temporary practice letter if:

- The Board previously approved the primary supervising physician to supervise one or more physician assistants in the performance of the requested advanced duty; **AND**
- The Board previously approved the physician assistant to perform the advanced duty.

If eligible, please complete Appendix A attached to this application.

Appendix B— Advanced Procedures: The advanced procedures list is meant to be used as a guide in determining what is considered an advanced procedure. This list is not all inclusive. If you have any questions about a procedure that is not on this list, please contact the Board.

Appendix C—Cosmetic Regulations: Physicians delegating cosmetic procedures must meet the criteria outlined in COMAR 10.32.09.

IMPORTANT NOTICE

- The Board is no longer required to provide prior approval of a delegation agreement containing advanced duties for physician assistants who are employed by accredited hospitals and accredited ambulatory surgical facilities if the facility meets certain criteria.
- A PA credentialed by an accredited facility may begin working after the Board receives the completed delegation agreement with the advanced duties and acknowledges receipt of the delegation agreement containing advanced duties.
- For non-accredited hospitals, non-accredited ambulatory surgical facilities and other types non-accredited practice settings, PAs must obtain prior Board approval before they begin practicing any advanced duty. PAs in these practice settings are required to submit training and education documentation.
- Pursuant to §15-302.1(e), the Board is authorized to disapprove any delegation agreement not meeting the requirements of the law or if the Board believes that a PA is unable to perform the delegated duties safely.
- A primary supervising physician is required to obtain the Board's approval of a delegation agreement before the physician assistant may administer, monitor or maintain general anesthesia or neuroaxial anesthesia, including spinal and epidural techniques under the agreement.

PLEASE KEEP A COPY OF YOUR ADDENDUM

MARYLAND BOARD OF PHYSICIANS
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BALTIMORE, MD 21215
www.mbp.state.md.us

DELEGATION AGREEMENT ADDENDUM FOR ADVANCED DUTIES

1. PRACTICE SETTING: Please choose one.	
Hospital	Ambulatory Surgical Facility
Private Practice/Other	
Is the facility/practice accredited? Yes No	
If yes, please provide the name of the accrediting agency: _____	
2. PHYSICIAN ASSISTANT INFORMATION: TYPE OR PRINT LEGIBLY	
Maryland License #:	
Last Name, (Suffix, Jr., III):	First Name:
Middle Name/Initial:	Maiden Name:
3. PRIMARY SUPERVISING PHYSICIAN INFORMATION: TYPE OF PRINT LEGIBLY	
Maryland License #:	
Last Name, (Suffix, Jr., III):	First Name:
Middle Name/Initial:	Maiden Name:
4. PRACTICE LOCATION: Please use a separate sheet of paper for additional locations.	
Facility/Practice Name:	
Department:	
Address:	
City:	State:
Zip code:	
5. PRACTICE CONTACT INFORMATION: Notification, approval or temporary practice letters may be emailed to the PA and the primary supervising physician. Please provide a valid email address.	
Home #:	Work #:
Fax #:	Cell #:
PA's Email Address:	Primary Supervising Physician's Email address:

6. SCOPE OF PRACTICE: Please choose the appropriate scope of practice.

Addiction Medicine Adult Critical Care Allergy / Immunology Anesthesiology Cardiology Cardiovascular Surgery Dermatology Emergency Medicine Endocrinology Family Medicine Geriatrics Gastroenterology & Hepatology Hospital Medicine Internal Medicine Infectious Disease Neonatology Nephrology Neurology Neurology Neurosurgery	OB/GYN Occupational Medicine Oncology Ophthalmology Orthopedic Orthopedic Surgery Otolaryngology (ENT) Pain Management Pathology Pediatrics Pediatric Critical Care Pediatric Surgery Plastic Surgery Psychiatry Public Health Preventative Medicine, General Physical Medicine & Rehabilitation Pulmonology Radiology	Radiation Oncology Rheumatology Sleep Technology Surgery, General Transplant Surgery Thoracic Urology Vascular Surgery OTHER _____
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7. DELEGATED ADVANCED DUTY (IES): Please list the procedure(s) that are being delegated to the physician assistant. **Examples: Cosmetic procedures (botox injections, laser hair removal, etc.), lumbar punctures, central/arterial line insertions, endoscopic procedures, stress testing, etc.**

8. Has the health care facility approved the PA to perform the requested procedure(s)?

- A. YES— Attach a copy of an approved delineation of hospital privileges that has been approved by the hospital/ambulatory surgical center’s governing body, e.g. Board of Trustees, President/CEO.
- B. NO— Attach a copy of the procedure logs* for each requested procedure showing at least 10—25 successful procedures. Include the dates of procedure and type of procedures. (200 for stress tests)
- C. N/A— Attach a copy of the procedure logs* for each requested procedure showing at least 10—25 successful procedures. Include the dates of the procedure and type of procedure. (200 for stress tests)

***The name and signature of the PA and the training/supervising physician should be on all procedure logs.**

9. QUALIFICATONS OF PHYSICIAN ASSISTANT (PA): Please describe, **in detail**, the additional training and education that prepared the PA to perform the requested procedures. **If applicable, attach copies of training certificates or other supporting documentation.** (PAs who will be performing *cosmetic procedures* must meet the requirements of COMAR 10.32.09 *Delegation of Cosmetic Procedures*. See Appendix C)

10. QUALIFICATIONS OF PRIMARY SUPERVISING PHYSICIAN (PSP) OR ALTERNATE SUPERVISING PHYSICIAN (ASP): If the delegated medical acts are outside of the PSP’s scope of practice, describe the qualifications of the PSP or ASP to perform and supervise the PA in performing the requested procedures. *PSPs/ASPs delegating cosmetic procedures must meet the requirements of COMAR 10.32.09 Delegation of Cosmetic Procedures. See Appendix C*

11. SUPERVISION: Which of the following best describes the continuous physician supervision methods to be utilized when the PA is performing the advance duty/procedure. Please check all that apply. **(The Board may require the supervising physician to be on-site at all times during certain procedures.)**

ON-SITE

WRITTEN INSTRUCTIONS

ELECTRONIC MEANS

ALTERNATE SUPERVISING PHYSICIAN

12. PRIMARY SUPERVISING PHYSICIAN ATTESTATION:

I ATTEST THAT:

- a. The PA is competent to perform this procedure.
- b. All medical acts to be delegated to the physician assistant are within my scope of practice or the scope of practice of a designated alternate supervising physician and are appropriate to the physician assistant’s education, training, and level of competence.
- c. I accept responsibility for any care given by the named physician assistant.
- d. In non-emergent situations, the policy of my practice is to notify patients in advance (ideally at the time of scheduling), if a physician assistant will be the treating practitioner.
- e. The policy of my practice is that either the physician assistant or I discuss the nature and purpose of the proposed treatment or procedure; the risks and benefits of not receiving or undergoing the treatment or procedure; alternative treatments and procedures; and risks or benefits of alternative treatments or procedures with all patients.
- f. If I delegate dermatological procedures to the physician assistant, I will perform the initial evaluation, develop a treatment plan with the physician assistant and provide immediately available supervision* while the physician assistant is performing the procedure(s).
- g. If I delegate cosmetic medical procedures to the physician assistant, I will perform the initial evaluation develop a treatment plan with the physician assistant and provide immediately available supervision* while the physician assistant is performing the procedure(s). *I have read and understood the regulations for delegation of cosmetic procedures —COMAR 10.32.09. See Appendix C*
- h. Consent forms meet the AMA standard guidelines.
- i. Under penalties of perjury, the contents of the foregoing document are true to the best of my knowledge, information and belief.

Primary Supervising Physician (Print legibly)

Primary Supervising Physician (Signature)

Date

*Immediately available supervision means in person, by telephone or other electronic means.

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TEMPORARY PRACTICE LETTER FOR ADVANCED DUTIES
(For delegation agreements with advanced duties that require prior Board approval)

INSTRUCTIONS: COMPLETE THIS PAGE AND ATTACH IT TO THE COMPLETED DELEGATION AGREEMENT ADDENDUM FOR ADVANCED DUTIES APPLICATION ONLY IF YOU MEET THE CRITERIA FOR A TEMPORARY PRACTICE LETTER.

A physician assistant may request a temporary practice letter if the following conditions are met: (1)The Board previously approved the primary supervising physician to supervise one or more physician assistants in the performance of the requested advanced duty; **AND** (2) The Board previously the physician assistant to perform the advanced duty.

A physician assistant and primary supervising physician **will not** qualify for a temporary practice letter if: (1) The primary supervising physician has never been approved by the Board to supervise a physician assistant in the performance of the requested advanced duty; **OR** (2) The Board never approved the physician assistant to perform the requested advanced duty.

Please complete all of the information in items 1—6.

1. Name of the physician assistant (PA) requesting the temporary practice letter:

2. Date Board approved PA to perform requested procedure(s):

3. Name of the primary supervising physician (PSP) requesting the temporary practice letter:

4. Date the Board approved the PSP to supervise one or more PAs to perform the requested procedure(s).

5. Name of the PA the PSP supervised in the performance of the procedure:

6. List the procedure(s) for which you are requesting a temporary practice letter.

ADVANCED PROCEDURES BY SPECIALTY

The advanced procedures list is meant to be used as a guide in determining what is considered an advanced procedure. This list is not all inclusive. Please consider using the listed terminology where appropriate. If you have any questions about a procedure that is not on the list, please contact the Board. If you wish to apply for advanced procedures, please go to the Board’s website at https://www.mbp.state.md.us/forms/della_adv_duties.pdf and download the Delegation Agreement for Advanced Procedures Form. *Note: Peripherally inserted central catheter (PICC) procedures are no longer considered advanced procedures.*

Cardiology
Aorta Ultrasound
IABP (Insertion, Manipulation, Removal)
Stress Tests (Pharmacologic and Exercise)
Cardio-Thoracic
Vein Harvesting (Open, Endoscopic)
Thorocostomy/Chest Tube Insertion
Tracheal Endoscopy
Thorocentesis (with/without ultrasound)
Vascular Access (Venous, Arterial)
Critical Care Medicine
Aorta Ultrasound
Tunneled Central Vascular Access (Arterial/Venous, with/without ultrasound)
Non-Tunneled Central Vascular Access
Thoracostomy (Chest Tube Insertion)
Laryngoscopy
Endotracheal Intubation
Lumbar Puncture with/without fluoroscopic guidance
IABP (Insertion, Manipulation, Removal)
Paracentesis (with/without ultrasound)
Sigmoidoscopy
Suprapubic Bladder Taps
Thoracentesis (with/without ultrasound)
Resuscitation of Neonate
Shunt Tap
Neonatal IV Insertions
Conscious Sedation (cannot be performed simultaneously with any other duty or procedure)
Dermatology
Ablative and Non-Ablative Laser Surgery
Chemical Peels
Dermaplaning

ADVANCED PROCEDURES BY SPECIALTY CONTINUED

Excision and Repair of Malignant Lesions
Skin Excisions
Dermatology (Cosmetic)
Ablative and Non-Ablative Laser Surgery
Body Contouring
Botulinum Toxin (A/B) Injections
Chemical Peels
Collagen Injections
Dermaplaning
Radiofrequency Body Contouring
Excision and Repair of Malignant Lesions
Intralesional Injections
Mesotherapy
Microneedling
Skin Excisions
Tattooing (Nipple Areolar Complex)
Ear, Nose and Throat
Laryngoscopy
Nasal Endoscopy
Tympanic Injections
Emergency Medicine
Aorta Ultrasound
Tunneled Central Vascular Access (Arterial/Venous with/without ultrasound)
Non-Tunneled Central Venous Access
Arthrocentesis (with/without fluoroscopic guidance; with/without ultrasound guidance)
Bone Marrow Aspiration and/or Biopsy
Thoracostomy (Chest Tube Insertion)
Closed Reduction of Fractures - Specify Locations
Closed Reduction of Dislocations (shoulders, fingers, toes and forearms are core duties) Specify Locations
Critical Care Bedside Ultrasound
Endotracheal Intubation
Focused Abdominal Sonography in Trauma (FAST)
Gastrostomy/Gastrojejunostomy Exchange/Replacement
Lumbar Puncture (with/without fluoroscopic guidance)
Nonfluoroscopic X-Ray procedures of the extremities , anterior, posterior & lateral, not Including the head, utilizing the Mini C-Arm
Paracentesis (with/without ultrasound guidance)
Suprapubic Bladder Taps
Thoracentesis (with/without ultrasound)
Endocrinology
Thyroid Biopsy
Gastroenterology
Paracentesis (with/without ultrasound)
Fistula Tubes (insertion and removal)

ADVANCED PROCEDURES BY SPECIALTY CONTINUED

Gynecology and Obstetrics
Biopsy (Cervical, Endometrial)
LEEP
IUD Insertions and Removal
Contraceptive Implants (Insertion and removal)
Insemination
Saline Sonogram
Circumcision
Culdocentesis
Hysterosalpingogram
Interventional Radiology
Aorta Ultrasound
Tunneled Central Vascular Access
Non-Tunneled Central Vascular Access
Tunneled Drains (Insertion/Removal) Specify Sites
Bone Marrow Aspiration and/or Biopsy
Thoracostomy (Chest Tube Insertion)
Fistulogram with Angioplasty (Dialysis Access Evaluation and Management)
Arthrocentesis (with/without ultrasound, with/without fluoroscopic guidance) Specify Sites
Lumbar Puncture (with/without fluoroscopic guidance)
Myelogram
Focused Abdominal Sonography in Trauma (FAST)
Gastrostomy/Gastrojejunostomy Tube Exchange/Replacement
Nephroureterostomy Exchange/Replacement
Paracentesis with/without ultrasound guidance
Percutaneous Biliary Drainage Catheter Exchange
Thoracentesis
Neurosurgery
Lumbar Puncture (with/without fluoroscopic guidance)
Myelogram
Shunt Taps
Oncology and Hematology
Administration of Intrathecal Chemotherapy
Bone Marrow Aspirate and/or Biopsy
Bone Marrow Harvest
Conscious Sedation (Conscious sedation cannot be performed simultaneously with any other duty or procedure)
Orthopaedics/Rheumatology
Nerve Block (with/without ultrasound guidance)
Insertion Skeletal Traction Pins
Arthrocentesis (with/without fluoroscopic guidance, with/without ultrasound guidance) Specify Sites
Arthrogram with fluoroscopic guidance Specify Sites
Greater Trochanteric Bursal Injections
Bone Marrow Aspirate and/or biopsy

ADVANCED PROCEDURES BY SPECIALTY CONTINUED

Botulinum Toxin (A/B) Injections
Closed Reduction of Fractures – Specify Locations
Closed Reduction of Dislocation (shoulders, fingers, toes and forearms are core duties) Specify Locations
Myofascial Injections
Trigger Point Injections
Removal of External Fixation Devices
Nonfluoroscopic X-Ray procedures of the extremities , anterior, posterior & lateral, not including the head, utilizing the Mini C-Arm
Pain Management
Botulinum Toxin (A/B) Injections
Arthrocentesis
Epidural Injections (with/without fluoroscopic guidance)
Myofascial Injections
Trigger Point Injections
Nerve Blocks (with/without ultrasound guidance)
Pediatrics
Insertion of Umbilical Catheter
Neonatal Resuscitation
Newborn Circumcision
Physical Medicine and Rehabilitation
Nerve Block (with/without ultrasound guidance)
Arthrocentesis (with/without fluoroscopic guidance, with/without ultrasound guidance Specify Sites)
Arthrogram (with fluoroscopic guidance) Specify Sites
Greater Trochanteric Bursal Injections
Botulinum Toxin (A/B) Injections
Epidural Injection Under Fluoroscopic Guidance
Myofascial Injections
Trigger Point Injections
Psychiatry*
* All psychiatric acts delegated by a Psychiatrist, including but not limited to the following:
Advanced Psychopharmacologic Treatment
Behavioral Therapy of Psychiatric Disorders
Conduct Diagnostic Assessments, Psychopharmacological Interventions and Behavioral Interventions
Evaluation and Basic Pharmacologic Treatment of Patients With Psychiatric Disorders in a Psychiatric Setting
Psychotherapy

ADVANCED PROCEDURES BY SPECIALTY CONTINUED

Surgery – General
Tunneled Central Vascular Access
Non-Tunneled Central Vascular Access
Urology
Cystoscopy
Nephroureterostomy Exchange/Replacement
Suprapubic Bladder Taps

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

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

10.32.09.01 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.

10.32.09.02 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;
 - (iv) Microdermabrasion device; and
 - (v) Devices used for the injection or insertion of foreign or natural substances into the skin, fat, facial tissue, muscle, or bone.

COMAR 10.32.09

(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) Deep skin peels;

(v) Skin treatments with phototherapy;

(vi) Microdermabrasion;

(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) "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.

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

(10) "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.

(11) "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.

(12) "Physician assistant" means a physician assistant with a current certificate to practice in Maryland.

COMAR 10.32.09

10.32.09.03 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.

10.32.09.04 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.

10.32.09.05 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.

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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.

10.32.09.06 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.

10.32.09.07 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.

10.32.09.08 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.

10.32.09.09 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.

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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

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