

SERIES 10

Definition of Surgery to Include the Use of Lasers, Ionizing Radiation, Pulsed Light and Radiofrequency Devices

11-10-1. General

1.1. Scope.- W. Va. Code 30-3-4(3) defines the practice of medicine and surgery as the diagnosis or treatment of, or operation or prescription for, any human disease, pain, injury, deformity or other physical or mental condition. W. Va. Code 30-3-7(a)(1) permits the Board of Medicine to adopt such regulations as are necessary to carry out the purposes of the article, which W. Va. Code 30-3-2 states in pertinent part is to provide for the licensure and professional discipline of physicians and podiatrists and to provide a professional environment that encourages the delivery of quality medical services within the state. Due to technological developments in surgery over the last twenty-five years, it is necessary for the health and welfare of the citizens of the state and in the public interest to clarify that the use of lasers, ionizing radiation, pulsed light and radio-frequency devices constitute surgery.

1.2. Authority.- W. Va. Code 30-3-7(a)(1).

1.3. Filing date.-

1.4. Effective date.-

11-10-2. Definitions.

2.1. For purposes of this rule, the following definitions apply:

a. "ablative treatment" means surgery that is expected to excise, burn, destroy or vaporize the skin below the stratum corneum.

b. "appropriate professional standards" means comprehensive surgical training and experience, including the management of complications, and the acquisition of certification in the appropriate surgical specialties by a member board of the American Board of Medical Specialties (ABMS) and credentials in the use of lasers, pulsed light and radiofrequency devices, ionizing radiation, or other similar techniques.

c. "appropriately educated and trained" means training that pertains to the physics and safety of light based medical devices and to performing any act or procedure that may alter, transpose or damage live human skin, including fundamentals of laser operation; bio-effects of laser radiation on the eye and skin; significance of specular and diffuse reflections; non-beam hazards of lasers; non-ionizing radiation hazards; laser and laser systems classifications; and control measures. A training program for each device must be attended, and maintenance of competency to perform non-ablative procedures through documented training and experience regarding the appropriate standard of care in the field of non-ablative procedures and the use of specific device(s).

d. "credentials" means a minimum of sixteen hours of basic training devoted to the principles of lasers, pulsed light devices and thermal, radiofrequency and other non-ablative devices, their instrumentation, physiological effects and safety requirements, including clinical applications of various wavelengths and hands-on

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#### 11-10-1. General

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#### 11-10-2. Definitions.

- 2.1. For purposes of this rule, the following definitions apply:
  - a. "ablative treatment" means surgery that is expected to excise, burn, destroy or vaporize the skin below the stratum corneum.
  - b. "appropriate professional standards" means comprehensive surgical training and experience, including the management of complications, and the acquisition of certification in the appropriate surgical specialties by a member board of the American Board of Medical Specialties (ABMS) and credentials in the use of lasers, pulsed light and radiofrequency devices, ionizing radiation, or other similar techniques.
  - c. "appropriately educated and trained" means training that pertains to the physics and safety of light based medical devices and to performing any act or procedure that may alter, transpose or damage live human skin, including fundamentals of laser operation; bio-effects of laser radiation on the eye and skin; significance of specular and diffuse reflections; non-beam hazards of lasers; non-ionizing radiation hazards; laser and laser systems classifications; and control measures. A training program for each device must be attended, and maintenance of competency to perform non-ablative procedures through documented training and experience regarding the appropriate standard of care in the field of non-ablative procedures and the use of specific device(s).
  - d. "credentials" means a minimum of sixteen hours of basic training devoted to the principles of lasers, pulsed light devices and thermal, radiofrequency and other non-ablative devices, their instrumentation, physiological effects and safety requirements, including clinical applications of various wavelengths and hands-on

practical sessions with devices and their appropriate surgical or therapeutic delivery systems.

e. "deep ablative treatment" means treatment below the dermo-epidermal junction.

f. "dermis" means that layer of skin which provides nutrient delivery and waste disposal via diffusion through the dermo-epidermal junction.

g. "dermo-epidermal junction" means the undulating basement membrane that adheres the epidermis to the dermis.

h. "direct supervision" means the opportunity and ability of the physician to exercise continuous control and direction over the services of non-physician practitioners and requires the physician to be physically present on the premises, within the office suite, and immediately available at all times the non-physician practitioner may be on duty.

i. "epidermis" means the layer of skin which is sustained and supported by the dermis.

j. "non-ablative treatment" means a surgery by any laser or intense pulsed light treatment or other energy source, chemical or modality that is not expected or intended to excise, burn, or vaporize the epidermal surface of the skin, including treatments related to laser hair removal.

k. "personal supervision" means the physician must be in attendance in the room throughout the performance of the procedure by a non-physician practitioner.

l. "stratum corneum" means the outermost layer of the epidermis.

m. "supervising physician" means a physician who holds a full and unrestricted medical license in West Virginia and meets appropriate professional standards.

n. "surgery" includes deep ablative, ablative and non-ablative treatments. Surgery includes the use of lasers, ionizing radiation, pulsed light and radiofrequency devices. Surgery includes alteration of the tissue by any mechanical, thermal, light based, electromagnetic, or chemical means.

*what does this include*

11-10-3. Supervision of non-physician licensed practitioners for deep ablative surgery.

- 3.1. A supervising physician may delegate the performance of deep ablative surgery to a practitioner, who is appropriately educated and trained, and licensed by the State of West Virginia, provided the surgery is performed under the personal supervision of the supervising physician and provided further the ablative treatments performed fall within the statutory and/or regulatory scope of the practitioner's profession.
- 3.2. The physician is responsible for assuring that the practitioner is licensed by the State of West Virginia, is practicing within the scope of his/her licensure, and only with the use of written protocols
- 3.3. The supervising physician is responsible for the examination of the patient and for authorizing the treatment plan, and the same is to be recorded in the patient's medical record prior to any initial deep ablative treatment.

- 11-10-4. Supervision of non-physician licensed practitioners for ablative surgery.
- 4.1 A supervising physician may delegate the performance of ablative surgery to a practitioner, who is appropriately educated and trained, and licensed by the State of West Virginia, provided the surgery is performed under the direct supervision of the supervising physician and provided further the ablative surgery performed falls within the statutory and/or regulatory scope of the practitioner's profession.
  - 4.2 The physician is responsible for assuring that the practitioner is licensed by the State of West Virginia, is practicing within the scope of his/her licensure, and only with the use of written protocols.
  - 4.3 The supervising physician is responsible for the examination of the patient and for authorizing the treatment plan, and the same is to be recorded in the patient's medical record prior to any ablative treatment.
- 11-10-5. Supervision of non-physician licensed practitioners for non-ablative surgery.
- 5.1 A supervising physician may delegate the performance of non-ablative surgery or procedures to non-physician practitioners, appropriately educated and trained, and licensed by the State of West Virginia, provided the treatments are performed under the direct supervision by the physician
  - 5.2 The physician is responsible for assuring that the practitioner is appropriately educated and trained, licensed in the State of West Virginia, is practicing within the scope of his/her licensure, and only with the use of written protocols.
  - 5.3 The supervising physician is responsible for the examination of the patient and for authorizing the treatment plan, and the same is to be recorded in the patient's medical record prior to any initial non-ablative treatment.
- 11-10-6. Utilization of non-physician licensed practitioners as assistants during the performance of surgery utilizing lasers, pulsed light and radiofrequency devices, chemicals, or ionizing radiation.
- 6.1. When a physician utilizes a non-physician practitioner during the performance of a deep ablative, ablative or non-ablative surgery involving lasers, pulsed light devices, radiofrequency devices, chemicals, or ionizing radiation, the assistant must be properly licensed to practice his or her profession and have been appropriately educated and trained for assisting the physician in such surgery.
- 11-10-7. Written protocols.
- 7.1. Written protocols for the purpose of this section means physician's order, standing delegation order, standing medical order, or other written order that is maintained on site. A written protocol must provide, at a minimum, the following:
    - a. A statement identifying the physician authorized to utilize the specific device and responsible for the delegation of the performance of the specified surgery;

- b. A statement of the activities, decision criteria, and plan the non-physician practitioner shall follow when performing delegated procedures;
- c. Selection criteria to screen patients for the appropriateness of non-ablative treatments;
- d. Identification of devices and settings to be used for patients who meet selection criteria;
- e. Methods by which the specified device is to be operated;
- f. A description of appropriate care and follow-up for common complications, serious injury, or emergencies as a result of the non-ablative treatment; and
- g. Documentation of decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made shall be recorded in the patient's chart pre-operatively.
- h. Documentation of a post-operative note shall be recorded within 24 hours after each treatment in the patient's medical record.

**11-10-8. Equipment Safety and Registration.**

- 8.1. Equipment used for the purposes stated in this rule must be inspected, calibrated and certified as safe to use according to the manufacturer's specifications and any use or operation of equipment named herein shall be in compliance with applicable federal law.

**11-10-9. Responsibility of Supervising Physician.**

- 9.1. The supervising physician maintains full responsibility to patients and the Board of Medicine for the manner and results of all treatment rendered.

**11-10-10. Applicability of Rule.**

- 10.1. This rule does not apply to:
  - a. hospitals, as defined in West Virginia Code 16-29B-3(e);
  - b. clinics organized in whole or in part for the delivery of health services to needy and indigent patients without charge; and
  - c. advanced practice nurses, advanced nurse practitioners, or certified nurse midwives, acting pursuant to a collaborative agreement with a licensed physician, and licensed physician assistants acting pursuant to job descriptions approved by the Board of Medicine, supervised by a supervising physician(s).